UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

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IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL No. 2804 Case No. 1:17-MD-2804
THIS DOCUMENT RELATES TO ALL CASES	Hon. Dan A. Polster

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HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VIDEOTAPED DEPOSITION OF EILEEN SPAULDING

Tuesday, February 5th, 2019
9:06 a.m.

Held At:
Ropes & Gray LLP
800 Boylston Street
Boston, Massachusetts

REPORTED BY:
Maureen O'Connor Pollard, RMR, CLR, CSR

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VIDEOGRAPHER: Robert Martignetti

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PROCEEDINGS

THE VIDEOGRAPHER: We are now on the record. My name is Robert Martignetti, I'm a videographer for Golkow Litigation Services. Today's date is February 5, 2019, and the time is 9:06 a.m.

This video deposition is being held in Boston, Massachusetts, In Re: National Opiate Litigation.

The deponent is Eileen Spaulding.

Counsel will be noted on the stenographic record.

The court reporter is Maureen Pollard, and will now swear in the witness.

EILEEN SPAULDING,
having been duly identified and sworn, was examined and testified as follows:

EXAMINATION

BY MR. GOTTO:

Q. Good morning, Ms. Spaulding.

A. Good morning.

Q. My name is Gary Gotto. We met briefly just before we went on the record. We've never met before today, correct?

A. Correct.

Q. Have you ever given a deposition previously?

A. No.

Q. Okay. Well, we will -- just a few items by way of background. Please let me finish my questions if you can, and I'll certainly try to let you finish your answers before so we don't speak over each other.

If any of my questions are unclear to you in any way, let me know and I'll do my best to clarify them.

A. Okay.

Q. If you answer a question without asking for a clarification, I'll assume you felt like you understood it. Okay?

A. Yes.

Q. And this is kind of a large table so I'll try to keep my voice up so we can all hear each other. But I'm not shouting, I'm just trying to --

A. I understand.

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Q. I'm pretty sure we can all be heard.

We will take breaks periodically today, but if you need a break at any point, as long as there's not a question pending, just let me know, and we'll accommodate that. Okay?

A. Okay.

Q. By whom are you employed?

A. Mallinckrodt.

Q. And what's your business address?

A. 172 Railroad Avenue, Hobart, New York 13788.

Q. And when did you first become employed at Mallinckrodt?

A. December of 1998.

Q. Before we get into your Mallinckrodt employment, just a little bit of background. Describe for me briefly your post-high school education.

A. So I have an associate's in computer information systems technology from BYU. And I went into the workforce for Elastic Stop Nut for approximately two years after graduation. I then worked for J.L. Hammett School Supplies as a customer service rep for ten years, PSE&G as a customer service rep for approximately two years, and then I relocated to New York and started with Mallinckrodt.

Q. Okay. What is PSE&G?

A. Public Service Electric & Gas. It's the electric company for the State of New Jersey.

Q. Okay. And do you hold any professional licenses or certifications?

A. No.

Q. Approximately when did you get your associate's degree?

A. I graduated in 1990.

Q. Okay. All right. And prior to Mallinckrodt did you have any employment history that was related in any way to the pharmaceuticals industry?

A. No.

Q. In your undergraduate work did you take any coursework that related to the pharmaceuticals industry?

A. No.

Q. Have you done any other formal -- apart from on-the-job training or internal

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training programs provided at Mallinckrodt, any other educational programs that you've taken that relate in any way to the pharmaceuticals industry?

A. Not sure I understand what you mean. Like DEA training seminars?

Q. That would be -- let me -- the pharmaceuticals industry -- well, let's be as broad as we can. That relate to pharmaceuticals in any way, so that would include anything related to DEA training or the Controlled Substances Act, anything of that nature.

A. Yes. So I've attended several DEA pharmaceutical training seminars sponsored by the DEA; pharmaceutical industry conferences also sponsored by DEA; HDMA, which is now known as HDA, two of their conferences; and BuzzeoPDMA, now IQVIA, I've attended multiple industry conferences.

Q. Okay. And have those all been during the time you were employed by Mallinckrodt?

A. Yes.

Q. Okay. We'll get into that in just a bit.

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Tell me what you did -- and I don't want you to disclose any communications with your counsel, but what did you do to prepare for today's deposition?

A. I met with my counsel.

Q. Okay. And how many times did you meet with counsel?

A. Three.

Q. And approximately when did you meet with counsel?

A. Two in January, and one yesterday.

Q. And were those personal meetings or telephonic?

A. Personal.

Q. And who was present?

A. Kate and Andrew.

Q. No one else?

A. No.

Q. Approximately how long did each one of the meetings last?

A. Seven to eight hours.

Q. And you can just answer this yes or no. Did you review any documents during those meetings?

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A. Yes.

Q. And did any of those documents refresh your recollection in any regard?

A. Yes.

Q. And in what regards can you recall your recollection being refreshed?

A. Well, once I'd read the e-mail, then it would remind me of what the topic or the subject matter was.

Q. Okay. Was there any particular matter you can recall reviewing a document and having that document refresh your recollection as to a specific subject matter or event?

MR. O'CONNOR: I'm going to object, and instruct the witness not to answer to the extent it would get into which particular documents we were looking at which would be protected by the attorney/client communication privilege and work product doctrine.

BY MR. GOTTO:

Q. So again, and I think this is consistent with your counsel's instruction, I'd like you to tell me not the document itself but just the subject matter, what the event or the

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subject matter as to which you can recall your recollection being refreshed by reviewing a document.

MR. O'CONNOR: You can answer at a general level.

A. Whatever the subject was of the particular document I would remember upon reading it.

BY MR. GOTTO:

Q. Sure. Okay.

Fair to say, then, there's not a specific thing that comes to your mind as you're sitting here today of, for example, reviewing a document and having the sensation of oh, gee, I forgot all about that meeting but now that I review this document I remember there was such a meeting, or anything of that nature that would be more specific than just a general, well, I see a document and that at some level, you know, causes me to better remember something that happened some years back?

A. No.

Q. Okay. Have you reviewed any transcripts of any deposition testimony given by

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any of the witnesses in this matter?
A. No.
Q. Have you had -- well, have you spoken to anyone who has given a deposition in this matter with respect to their deposition?
A. Only that they had been deposed. Nothing of the subject matter.
Q. Okay. And who did you speak to in that regard?
A. Karen Harper.
Q. Anyone else?
A. No.
Q. Have you reviewed any of the papers that have been filed in court related to this litigation, including any of the complaints filed by any of the plaintiffs?
A. No.
Q. Are you aware that there's in excess of a thousand complaints that have been filed by various governmental entities, counties, municipalities, etcetera, relating to the opioid epidemic?
A. Yes.
Q. And again without divulging any

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communications with counsel, how did you first become aware of that?
A. It's only through counsel that I am aware of that.
Q. Is it a subject -- the litigation, is that a subject that you've had any conversations with anyone else at Mallinckrodt, again apart from communications with counsel?
A. No.
Q. Have you taken any steps to preserve any documents that might in any way relate to the subject matter of the opioid litigation?
A. So we have a document preservation notice that's been issued, so all documents have been preserved.
Q. Okay. But -- and that would apply to documents that, for example, are on Mallinckrodt servers or on your work computer, that sort of thing?
A. I can only speak to my work computer.
Q. Okay. In terms of -- do you have a personal computer at home?
A. Actually, no, I don't.
Q. You don't.

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Okay. Do you have at home any paper files that in any way relate to your work at Mallinckrodt?
A. No.
Q. And have you at any time?
A. No. I apologize, I step back. I have taken work home previously to complete and bring back to work the next day.
Q. Okay. But in terms of maintaining a file in a file --
A. No, absolutely --
Q. -- cabinet at your home or anything like that, that's not something that you do?
A. No, absolutely not.
Q. Okay. Well, let's talk about your employment at Mallinckrodt. I'd like first to just get a general sense of the positions that you've held over the years. I realize you've been there a long time and you may be a little fuzzy on particular dates, and that's fine. This isn't a memory contest. And we'll look at some documents that may pin down some dates from time to time as we go through today.
But just at a general level, if you

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can tell me the positions that you've held over the years at Mallinckrodt.
A. Sure. I started in their packaging department as a packaging operator in 1998. I was in that department for approximately a year and a half, and I transitioned into the validations department. And I was with validations for approximately two years. And then in April of 2001, I transitioned into the compliance role.
Q. Okay. So prior to April of '01, in the packaging and validations positions, just tell me generally what responsibilities you had in those positions.
A. In packaging it was working on the line that puts the tablets and capsules into the bottles, running the machinery.
And then in validations it was executing protocols and taking samples to validate products for FDA approval.
Q. Okay. And did you receive any training with respect to either of those positions?
A. Yes.

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Q. What was the nature of the training?
A. So in packaging would have been on-the-job training, classroom training, SOP training.
The same for validations. Validations, I had in the beginning a one-on-one trainer that would show me how to take samples and execute the protocols, how to write reports.
Q. And what is SOP training?
A. Reading SOPs, standard operating procedures. We have a computer system that assigns us SOPs based on our curriculum, and we read those, and in some cases take -- there's a quiz associated with those SOPs.
Q. Okay. You said April of '01 you transitioned to a compliance role. What was the compliance role that you transitioned into?
A. So in April of 2001, the reason I remember the date is because that's when our distribution center opened, and a newly created position of compliance investigator -- excuse me, compliance investigator was created in which I did the ARCOS reporting. I would investigate any losses in transit with the carriers, made

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sure our reports were filed on time, handled destruction of the pharmaceutical waste, and any other tasks as assigned.
Q. Okay. And you indicated this was a new position that was created in '01, is that correct?
A. Yes.
Q. And it was related to the establishment of the distribution center?
A. Yes, it was an additional license that was started at the Hobart site.
Q. And what was the nature of the additional license?
A. A distribution center. So previous to that we had only had a manufacturing DEA license and an analytical license. The addition of the distribution center in Hobart created the need to have a DEA distributor license and a DEA exporter license.
Q. And so the DEA distributor license, what did that permit Mallinckrodt to do that it hadn't done previously?
A. To distribute either Mallinckrodt-made products or products that were made by other

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manufacturers on behalf of Mallinckrodt.
Q. So prior to having the distributor license, Mallinckrodt had a license to manufacture controlled substances, correct?
A. Yes.
Q. And so it would then -- what would it then do with the controlled substances after it manufactured them?
A. It would send them to St. Louis for distribution.
Q. And did Mallinckrodt in St. Louis have a distribution license?
A. Yes.
Q. Okay. So the distributor license that was obtained in '01 was for the Hobart facility?
A. Yes.
Q. Okay. So when you took the position of compliance investigator, to whom did you report at that time?
A. Liz McPhail.
Q. And what was her position?
A. Purchasing manager.
Q. And for how long did that reporting relationship continue?

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A. I don't recall exactly.
Q. Was it some number of years?
A. A few years.
Q. Okay. And to whom did you report after you no longer reported to Ms. McPhail?
A. To the materials manager.
Q. And who was that?
A. Tim Bach, and then later Aaron Nikolaus.
Q. And for how long did those reporting relationships continue?
A. Again, a few years.
Q. And after that to whom did you report?
A. Karen Harper.
Q. Do you recall approximately when you began reporting to Ms. Harper?
A. 2008 sometime.
Q. And do you recall what her position was at that time?
A. Senior manager of controlled substances compliance.
Q. And for how long did your reporting relationship with Ms. Harper continue?
A. I'm still reporting to Karen Harper.

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Q. Okay. The position compliance investigator which you indicated was a new position when you took it in '01, did you receive a written job description or a list of responsibilities?
A. I don't remember.
Q. How did you come to have that position? Did you apply for it?
A. Yes. There was a posting internally which I applied and was interviewed and awarded the position.
Q. Do you recall by whom you were interviewed?
A. Liz McPhail was one of them. I don't remember who the others were.
Q. And did you have an understanding at the time as to what in your background qualified you for that position?
A. I guess just being an operator and familiar with our processes and our products.
Q. And you listed a few items that you had responsibility for, for example, ARCOS reporting. What was ARCOS reporting?
A. ARCOS reporting is -- at that time we

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were reporting quarterly all of our distributions to our next downstream direct customer.
Q. And those reports went to whom?
A. DEA.
Q. Okay. And so was it your -- you had responsibility for completing those reports, is that right?
A. For the distributor license.
Q. And do you continue to have that responsibility today?
A. Yes.
Q. Tell me what the -- just in general what the ARCOS report reports to the DEA?
A. So ARCOS is Automation Reports Consolidated Ordering System, and it is all of our receipts, so any product that we bring in we record and any product we ship out we record, and so it's acquisitions and dispositions.
Q. And how do you go about gathering the data that you include in that report?
A. For what time period? Because it's changed.
Q. Okay. Fair enough. Maybe you can

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tell me at the beginning how you did it, and then how that process changed over the years.
A. So at the beginning it was a -- basically a -- we call it DDS, dangerous drug system, would compile all of the data for the receipts, and the shipments, and download it into ARCOS format, which is -- I don't know, it's a specific format, and then we would download it onto disk and mail that disk to DEA quarterly. Over time we started reporting monthly at the request of DEA. And then in time DEA had enhanced their systems to be able to report online.
So now we have two computer systems that we merged together, our manufacturing and our distribution center inventory systems, we merged those together into a file that converts to ARCOS format, and we upload it via a portal on a monthly basis.
Q. Okay. When did it -- did the reports convert from quarterly to monthly, if you remember?
A. I don't remember exactly when.
Q. Is there anyone else involved in the

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process of compiling the data and transmitting the ARCOS reports?
A. For which DEA license?
Q. Well, are you involved in the ARCOS reporting for other than the Hobart distribution license?
A. Now I am. Back at the beginning of my role I was not. Now, as manager, there's another person that works under me, and she does the manufacturing DEA ARCOS, and I do the distributor ARCOS.
Q. Okay.
A. And we're backup for each other.
Q. Okay. And when did that come to be that you had someone working under you that you just described?
A. In April of 2017.
Q. So prior to the time that you had this person working under you on the manufacturing license, was there anyone else involved in compiling or transmitting the ARCOS reports that you had responsibility for?
A. No.
Q. Was there any process in place to

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review the ARCOS reports that you prepared for accuracy or completeness?
MR. O'CONNOR: Object to form.
A. I'm not sure I understand. It's a computer download.
BY MR. GOTTO:
Q. Okay. So let's go back to when it was a physical report that you were preparing and sending to the DEA. There was an actual paper report at some point, correct?
A. No, it was a file that we just put onto a disk. But ARCOS requires it in a specific format, and it's not human readable. It's a number of fields all pressed together.
Q. Okay. So you would input the data into that format, is that how it would be prepared?
A. It would -- we have a computer program that downloads it into that format.
Q. And so your personal involvement in the preparation of the reports, what does it consist of?
A. Executing those -- a series of steps that allows the computer to pull down the sales

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data and convert it to ARCOS format, and then if there's any manual transactions or errors or returns, I would enter those into the computer system which would download into that ARCOS format.
Q. Okay. So, and is that a description that's still current?
A. Yes.
Q. Okay.
A. And it's the same for both DEA licenses.
Q. Okay. So is there any process in place at Mallinckrodt, or has there been at any point, to review any of the steps that you take that you just described for accuracy, errors, completeness, etcetera?
MR. O'CONNOR: Object to form.
A. Not that I'm aware of.
BY MR. GOTTO:
Q. Okay. Is the ARCOS reporting function something that is a subject of any annual goals that you set or reviews that you receive?
A. It was earlier in my career.
Q. Okay. Goals or reviews or both?

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A. Both, you know, that the reports were filed on time.
Q. Okay. And other than timeliness, any other aspect of the reporting that was subject of any goals or reviews?
A. Not that I can recall.
Q. Do you have an understanding of the purpose of the -- from the DEA's standpoint, do you have an understanding of the purpose for the ARCOS reports?
MR. O'CONNOR: Objection to form.
A. At a very high level.
BY MR. GOTTO:
Q. And what's that understanding?
A. Is that it reports all of the acquisitions and distributions. My ARCOS report tells DEA everything we've acquired and everything we've distributed. And then if there's error reports, DEA will send us -- after we file the report, DEA sends us an error report, and if there's errors in the ARCOS data, then we fix those errors on the next quarterly report, or now monthly report.
Q. And does that happen regularly, that

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there are errors?
A. Not regularly, but on occasion.
Q. And what's the nature of the errors typically?
A. If there's a keypunch of a wrong digit and a wrong character that the system has downloaded, or if a DEA number has been -- was missed.
Q. Okay. And the nature of the information that you submit in the ARCOS report, you indicated it's -- what you acquired and what you distributed, at what level of detail is that information? Is it by, for example, API, or how is it categorized?
MR. O'CONNOR: Object to form.
A. For which license?
BY MR. GOTTO:
Q. The distributor license.
A. So it's by finished goods, SKU, so the individual number of bottles, packaged unit, and so the number of bottles received and number of bottles shipped, if there was any returns from a customer for any reason, or if there's been any waste, scrap.

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Q. Okay. And the bottles received in the case of the Hobart facility, from whom would they be received?
A. They could be received from the Hobart manufacturing facility, or from an external manufacturer.
Q. Okay. And so that manufacturer, whether it's Mallinckrodt Hobart or another manufacturer, they would be reporting on a separate ARCOS report their receipt and then sale of those manufactured goods, correct?
A. Yes. Correct.
Q. And that's not a process you're involved in in the Hobart facility, correct, or at least until April, 2001 -- 2017, you were not involved in that process?
MR. O'CONNOR: Object to form.
A. No, I misunderstand.
BY MR. GOTTO:
Q. The process I'm referring to is whatever ARCOS report related to Hobart's manufacturing activities, that report is not something that at least until April of 2017 you had any involvement in, is that correct?

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A. I was aware of it. I would help if there was a problem. But I was not the primary person responsible for reporting.
Q. Okay. Do you know who was the primary person responsible for reporting?
A. Prior to 2005 was Sabrina Fountain, After 2005 was Carrie Johnson.
Q. Okay. And currently the person who does that reporting reports to you, is that correct?
A. Yes.
Q. And who is that?
A. Carrie Johnson.
Q. So since April of 2017, are you involved in actually working on the preparation of the manufacturing license ARCOS report for the Hobart facility?
A. No.
Q. Do you, in your capacity supervising Ms. Johnson, do you review anything -- any of the work that she does relative to that ARCOS reporting?
A. No.
Q. You indicated that prior to 2017, if

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there was a -- if there was an issue or problem with the manufacturing license ARCOS reporting at Hobart you would sometimes get involved in that. Do you recall any particular issues or problems that arose from time to time?
MR. O'CONNOR: Objection to form.
A. Nothing particular. If there was -- an error on the report came back and Carrie couldn't figure out what it was, I would help her.
BY MR. GOTTO:
Q. In any of the -- you indicated early on that there have been a number of DEA-sponsored seminars or other training sessions that you've attended. Has ARCOS reporting been a subject of any of those sessions?
A. Yes.
Q. And what's been the substance of that, that you can recall?
A. It was DEA training on the transaction codes and the format. That's where they introduced us to the new ARCOS portal for us to be able to upload and what direction they were

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moving in and, you know, what transaction codes to use for what specific business activity.
Q. Okay. One of the other subject matters you indicated you had responsibility for is losses in transit. What did you mean by that phrase?
A. So if the carrier -- if there was damage or a loss while the product was in transportation to the customer.
Q. Okay. And is that something that's the subject of a regular report, or is it something that's just reported on as it occurs?
A. Reported on as it occurs.
Q. And how do you -- how would you become aware of the circumstances that would then give rise to such a report?
A. We're either notified by the carrier that they have a box that was damaged in transit, or a customer may contact our customer service department and say they received a box that was damaged in transit.
Q. Okay. And so once you receive word of such an event, what do you do to act on that?
A. If there's just damage only, then we

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would notify the carrier, give them the tracking information, make them aware of the damage. Corporate tracks them on a scorecard. I don't know the details to that.

And if there was contents missing, then we would work with the carrier to find out what happened to those contents and if they can be recovered.

Q. And is that something you personally are involved in, working with the carrier when there's missing contents?

A. Yes.

Q. And so how do you go about determining whether those contents can be recovered?

A. We will contact our security contacts with the carrier, initiate an investigation, they will start looking for the product in their facilities and everywhere that package transitioned. And it's typically the box has busted open while handling on their automated machinery and a case has become separated, in which it goes to overgoods, and then overgoods notifies me that they have Mallinckrodt product. We bring it back to the distribution center and

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send it for destruction.

Q. And overgoods is what?

A. Overgoods is the department in which our specific carrier -- any loose box that's found anywhere within their system and they can't determine where it was coming from or where it was going to because it's not in its original shipping container with the labels goes to overgoods, and then they inventory it, and we'll have dedicated trace agents to be able to try to locate who was either the shipper or the recipient of that product.

Q. Okay. So if the -- do losses in transit ever result in a report that goes to the DEA?

A. Yes.

Q. Under what circumstances?

A. If the material is not located in overgoods we will file a DEA 106 report, notify them immediately.

Q. Okay. And is that something that you're responsible for preparing?

A. Yes.

Q. And what does the 106 report report to

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the DEA?

A. It's their loss/theft report. It gives the details around the shipment and the product and quantity that is unaccountable.

Q. And is there such a report prepared any time any amount of controlled substances is lost in transit and not otherwise accounted for?

A. I don't understand the question.

Q. Well, so the 106 report, let me ask it a different way, is that prepared on an event-by-event basis that there was a particular loss in transit that where a product cannot be accounted for ultimately and, therefore, that gives rise to a particular 106 report that goes to the DEA?

A. Yes.

Q. And would that be -- is there any minimum amount of missing product that if you fall below the minimum you don't have to do the 106 report, anything like that?

A. Mallinckrodt's policy is to report any controlled substances not accounted for.

Q. Okay. Even if it was one bottle?

A. Yes.

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Q. Or one pill?

A. Yes.

Q. Can you give me a sense for the frequency, and if this changed over time how it changed over time, the frequency of filing 106 reports with the DEA that you worked on?

A. There's not a frequency. It's if you have a loss that can't be accounted for, you report it.

Q. Sure. I understand.

In a typical, say, month period, do you have an estimate of how many 106 reports on average you would have filed?

A. In what time frame?

Q. Well, again, if it changed over time -- really the entire time that you've been responsible, but if it's changed over time, you know, how that's changed.

MR. O'CONNOR: Objection to form.

A. We had more frequent losses in transit when we were using one particular carrier service, so I don't remember exactly. I know that there was more, which is the reason we changed the carrier service and upgraded to an

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express service in which our packages got more prioritized handling and pre-alerts so that each station knew when a Mallinckrodt package was coming through so that they could watch it and make sure it was under CCTV coverage, and our 106s dropped dramatically. Currently I file maybe, rough estimates, I don't have my records in front of me, four to five a year.
BY MR. GOTTO:
Q. So the carrier that you changed from, who was the carrier that you had more loss experience with?
A. It was FedEx Ground service, which back in that -- in the early time was formerly known as RPS, Roadway Packaging Services. And they weren't handling our product appropriately and we were experiencing a lot of damages, so our corporate transportation team transitioned to FedEx Express services.
Q. Okay. Do you recall when that -- about when that transition occurred?
A. I don't recall exactly.
Q. Was it, say, before 2012?
A. Yes.

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Q. Before 2010?
A. It was mid 2000s. Could have been '5, '6, '7, '8.
Q. So probably before 2010?
A. Yes.
Q. Okay. And were the problems primarily damage, or were they losses that ultimately couldn't be accounted for?
MR. O'CONNOR: Object to form.
A. They were predominantly damages.
BY MR. GOTTO:
Q. Okay. And so am I understanding correctly if there's damage but the product is all accounted for, that doesn't result in a 106 report, correct?
A. It depends on whether it was recovered quickly, because we have to report within 24 hours. So if we could report -- if we could recover within FedEx within 24 hours and we knew they had the product, it was in as overgoods, then we would not file. If we couldn't locate the product within 24 hours, we would file.
Q. Okay. And what would happen if you couldn't locate within 24 hours so you filed the

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106, and then you subsequently find out from FedEx that they're able to locate the product, do you then update the DEA on that, or --
A. Yes. We file an amended DEA 106 and send the DEA a cover letter stating that the material has been recovered and brought back to the distribution center and destroyed.
Q. Okay. So your estimate, I realize it's a rough estimate, of four to five 106 reports a year for the last several years, are those 106 reports as to which ultimately the product was never actually recovered? Is that fair?
A. I don't know without looking at the records.
Q. Okay. That estimate of roughly four to five a year, would that go back to as far back as whenever it was that you made the transition away from FedEx Ground?
A. I'd have to look at the records. I know what currently, they're approximately four to five years -- or four to five a year. I don't recall specifically what they are prior, for past years.

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Q. Okay. So, for example, let's say that 2010 to 2014 time frame, do you have any sense of how -- of the average number of 106 reports that were filed in that time frame?
A. No, I don't.
Q. Okay. During the period of when you were using FedEx Ground, do you have a sense for approximately how many, on average, how many 106s on average were filed annually?
A. Not an exact number. It was significantly higher than what we currently have.
Q. Was it twice as many?
A. I don't remember exactly.
Q. Okay. I'd like to understand, and I realize since 2001 we're dealing with a long time period here and some of this is going to necessarily be, you know, a little fuzzy perhaps as to specific dates and that sort of thing, but I'd like to understand how your job responsibilities changed over the years, if they have changed. So if you can just -- let's start with sort of a general description of how those responsibilities have changed over the years.

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A. So I have received promotions throughout the years into different levels within the compliance group. I started out with just basic clerical, the ARCOS reporting, data entry of waste transactions, discrepancy reporting with the carriers. Then my responsibilities increased in which I took on facilitating and organizing the destruction of the waste, not just doing the data entry. Took on more responsibility in terms of just workload, still doing the clerical but then doing -- more involved with walk-throughs through the facility, learning more about CFR and the regulations, attended the training seminars, learned about quota, and then I was a compliance analyst for a length of time, and then promoted into senior controlled substance compliance coordinator, facilitated DEA audits, was the DEA contact, was on the CSOS working team when DEA was instituting CSOS to our electronic 222 forms, and then was promoted into the role of manager in April of 2017.

Q. Great. Thank you. Let's go through some of those items.

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I think we've -- the ARCOS reporting responsibility, I think you've already described, is a continuing one that you still have for the distribution license at Hobart, correct?

A. Yes.

Q. Apart from the testimony you've already given us this morning, is there any other aspect of ARCOS reporting that's been your responsibility?

A. Currently?

Q. Or at any time.

A. Well, currently the manufacturing is done by a person who reports to me, so I oversee that. But nothing else in regards to ARCOS.

Q. Okay. And waste data entry, which you'd indicated was an early on responsibility, is that something you still have responsibility for?

A. My team, but not myself.

Q. And what does that waste data entry consist of?

A. So we track every single tablet, powder, capsule of waste that's a controlled

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substance, and those get -- they're documented, weighed, documented on our destruction reports. We enter -- our team enters that into our computer system, which then currently sends all of the waste to a waste distributor for destruction by incineration.

Q. And you indicated your team still does -- is still responsible for that. Who on your team currently has that responsibility?

A. Carrie Johnson has the data entry portion.

Q. Okay. Next item you indicated was discrepancy reporting. What's that?

A. So that's what we were talking about earlier with the carriers -- excuse me, with the carriers that if there's any discrepancies in what we ship versus what the customer ordered, or if the customer ordered a wrong product or we shipped a wrong product in error, any difference than what was intended to be ordered.

Q. Okay. And so some of those discrepancies are the result of damage in transit, the sort of thing you discussed -- described a little earlier today. It sounds

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like sometimes there's a misfilling of an order, though. What happens in those situations?

MR. O'CONNOR: Objection to form.

A. Because of our cycle count program in the processes in the distribution center, we have not had in the last ten years a shipping error where we meant to ship sugar-free and we shipped cherry or something, because of the bar coding system.

Prior to that there could have been an instance where the wrong product was shipped, and then the customer would say, hey, we've received the wrong product, we'd make arrangements to issue them a 222 form, we would document what happened, that it was our mistake, how we fix it, and then would make sure that the customer had all of the documentation they needed to document what happened, that they received the wrong item, it was returned back to Mallinckrodt, we received the incorrect item, we sent it for destruction.

BY MR. GOTTO:

Q. Okay. And you also indicated sometimes the customer may have ordered the

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wrong item.
A. Frequently we have situations where a customer will enter the wrong item in their order entry screen. They want buprenorphine 8.2-milligram and they ordered buprenorphine 2.5-milligram and they get it and it's the wrong product and they have to send it back to us. And that's frequent we have customer ordering errors.
Q. Okay. And in that situation, is there any sort of report that gets generated when that happens, or --
A. The --
Q. -- how is it handled?
A. I apologize.
The discrepancy report would document what transpired, and then we would document appropriately what actions we took to rectify.
Q. Okay. And that discrepancy reporting, is that something that you're personally involved in?
A. Yes.
Q. Another item you mentioned was destruction of waste. Is that the process you

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have described a few moments ago where you shipped the waste to a reverse distributor for destruction?
A. Yes.
Q. And is that -- shipment of that waste, is that documented with the DEA somehow?
A. It's -- if they're C1 and 2s, they are documented by a 222 form; 3, 4s and 5s, a transfer of controlled substance form, and it is ARCOS reported as well.
Q. Okay. So the -- either the 222 form or the transfer form that you mentioned, are those things that you have responsibility for?
A. Yes.
Q. Is there a regular process for the destruction of waste, or is it handled on an as-needed basis?
A. Monthly we schedule a pickup by the reverse distributor to take care of all of the waste generated from the previous month because it has to be stored in cages and vaults, so if we don't have it removed monthly, we tend to run into space problems.
Q. Okay. Another thing you mentioned

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were walk-throughs. What did you mean by that?
A. So we go up on the manufacturing floor and just walk through the facility daily to make sure that materials are being stored in compliance with the regulations, there's nothing being left out, there's no residual powders anywhere they shouldn't be, everything is sealed. Just being there for questions for the floor, if somebody has a question, how do they handle something.
Q. Okay. And so when you say we do that daily, who is "we" in that setting?
A. I do it daily. When I'm not there, a member of my team will do it.
Q. So describe for me, if you would, the Hobart facility, just the physical setup relative to your office. For example, since you walk through it daily, about how large is the facility?
A. I'm not -- I don't know square footage or any of that kind of thing. It's a big facility, but I don't know the square footage.
Q. Is it multi-story?
A. Yes, there are multiple floors.

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Q. Okay. So the walk-through that you do every day, how long does it take you?
A. 45 minutes to an hour.
Q. Okay. Are there particular things you look for when you're doing the walk-through?
A. Just to make sure everything is stored appropriately and within compliance.
Q. And one of the -- actually right after the walk-throughs you indicated learning more about the CFRs and regulations, and part of your walk-through, I take it, is to satisfy yourself that the facility is in compliance with applicable regulations, correct?
A. To ensure we're always in compliance, yes.
Q. And so describe for me the process you've gone through over the years to learn about and stay current on the applicable regulations.
A. So I've read CFR a number of times. I refer to it often if there's questions. If we were unsure of an interpretation of CFR, we may have reached out for DEA to their field office for interpretation or asked them while they were

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on-site for an audit, so I've learned from DEA what their expectations are, what they want. I attended the DEA training seminars that are sponsored by DEA in which they go over their expectations or break down CFR into more detail.

We do practice exercises on quota at those training seminars, they talk about imports and exports, how to fill out the forms, and how to do the calculations in the way that they want them so that they can process them more efficiently.

Q. Okay. Is that a -- do you still go to the seminars that DEA sponsors?

A. When they have them. They haven't been having them as more -- as frequently as they did. They used to have them every other year, and it's been a couple of years since they've had them.

Q. Okay. So during the time since 2001 when you became involved in compliance, about how many DEA-sponsored trainings have you been to?

A. More than a dozen.

Q. And are these multi-day programs?

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A. Usually they're two days.

Q. And you also indicated you attended the Buzzeo training, correct?

A. Yes.

Q. How often have you done that?

A. Just about every year.

Q. Up to the current?

A. Yes.

Q. What's the subject matter that's typically covered at the Buzzeo conferences?

A. They usually have a DEA speaker that's talking about NPRMs and what's on their agenda and what they're working on. They'll have subject matter experts on state licensing, and different laws that individual states are enacting in regards to controlled substances. They'll have roundtable discussions on industry topics. It's usually a two-and-a-half-day conference.

Q. Okay. Are there particular, for example the roundtable discussions, particular ones that you make a point of participating in at these conferences?

A. Yes.

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Q. Which are those?

A. Suspicious order monitoring, state licensing, exports. DEA has an initiative with streamlining the Customs documentation through a database with exports.

Q. So let me be sure -- I just want to be sure I've covered all the various sort of formal DEA-related training conferences and seminars that you've gone to.

You indicated about a dozen or so of the DEA-sponsored programs, although there hasn't been one in the last at least couple of years, correct?

A. Correct.

Q. And the Buzzeo, those are one a year?

A. Annual, yeah.

Q. Okay. Are there other training programs of that type that you've attended?

A. NADDI, but not -- NADDI, they have DEA speakers sometimes, but it's more about what's going on in the industry.

Q. And do you attend the NADDI conferences regularly?

A. I have occasionally.

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Q. About how many times?

A. Half dozen roughly.

Q. How recently can you recall going to one?

A. Last year. I went to a NADDI conference last year.

Q. Are they annual?

A. They are.

Q. Okay. Apart from NADDI, Buzzeo, and the DEA-sponsored, any other ones you can think of?

A. Years ago I attended the Pharmaceutical Security Coalition, PSC, many years ago, and it was only once. It was more geared towards physical security.

Q. In one of your answers a moment ago you made reference to NPRM?

A. Notice of proposed rulemaking.

Q. Okay. Thank you.

Do you recall any particular proposed rules that were covered in any of the conferences you attended?

A. Recently there is one for paper. They're trying to eliminate the carbon 222

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forms, so there's been a Notice of Proposed Rulemaking for one-page 222 forms. And there was a recent one, but off the top of my head it's escaping me.
Q. Okay.
A. Quota, there's a recent NPRM regarding quota.
Q. You've mentioned quota a couple of times. What's been your responsibility over the years with respect to quota?
A. Initially I had very little to do with quota. In more recent years I've been involved with compiling and reviewing the quota letters for increases throughout the year. The initial quota requests are prepared by my team, and I review.
Q. When you say "quota," what do you -- just so the record is clear what we're talking about here, what do you mean by quota?
A. Quota is the DEA allocation system to -- for the manufacturing of controlled substances.
Q. And would your involvement be with respect to the manufacturing activities at the

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Hobart facility?
A. Yes, quota only applies to the manufacturing license. It doesn't apply to the distributor license.
Q. And is it specific to facility by facility?
A. Yes.
Q. Okay. And so to the extent there's a quota for Mallinckrodt St. Louis facility, that's not something you have involvement with, is that correct?
A. Correct.
Q. Okay. Do you know who has the corresponding role, the role that corresponds to your role at Hobart with respect to the St. Louis quota for manufacturing?
A. That would be my counterpart, Dave Hunter.
Q. Okay. And the quota that -- focusing on the Hobart-related quota that you do have responsibility for, when did you first have responsibility for quota?
A. So it was predominantly overseen by Karen Harper, it was compiled by Carrie Johnson,

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I would assist and review for a second set of eyes, and then Karen Harper ultimately approved the letter for submission. Carrie at that time prior to 2017 reported directly to Karen Harper.
Q. Okay. And so the actual submission, has that always been Ms. Harper's responsibility?
A. To review -- I need clarification of actual submission, entering into the database or --
Q. Yeah. Well, let me back up.
You said -- you made reference to your involvement being a second set of eyes. Was there any time when you had more involvement than simply being a second set of eyes?
A. Currently I do.
Q. Okay. And so when did you take on that additional responsibility?
A. When Carrie Johnson started reporting to me.
Q. In 2017?
A. Yes.
Q. Okay. So prior to 2017 when Ms. Johnson started to report to you, in the

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second set of eyes role that you mentioned, what did your activities consist of with respect to quota?
A. Remote -- reviewing it for grammatical content in terms of if I had heard through my role maybe we had taken on a new contract or been awarded business and Carrie hadn't included that in a request, I would remind her about that or let her know about that so it could be inclusive in the request advising DEA of all the information that we had available to us.
Q. Okay. And you indicated that initially you had very little responsibility for -- with quota, and that changed over time. Did you have more responsibility when you began reporting to Ms. Harper?
MR. O'CONNOR: Objection to form.
A. I don't understand the question.
BY MR. GOTTO:
Q. I'm just trying to understand when you started to have this additional responsibility, the second eyes review of the quota applications.
A. So that would have been -- I got more

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involved in roughly '14, '15, 2014, 2015. Carrie and I both reported to Karen. Carrie had her set of responsibilities. I had my set of responsibilities. But in roughly '14 or '15, I was cross-training more and taking on more responsibilities to advance to manager, so in that learning I needed to learn more about quota, so then I started getting more involved in quota.

Q. Okay. So what did you do to learn more about quota?

A. More thorough on the letters, understanding them, learned more about the market and the dynamics that go on in the supply chain, and the quota section training on the -- from the DEA seminars.

Q. And so the DEA seminars on quota training, what are the topics they cover in that context?

A. Research versus manufacturing, where does the quota belong, when do you start needing quota. Karen mentored me because she had a lot of experience with quota.

Q. So when you say "research versus

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manufacturing," what did you mean by that?

A. So there's researcher license and there's manufacturing licenses, and quota is not required on a research license but it is required on a manufacturing license, so what project development work can be executed under a research license not requiring quota, and what project development work needs to be executed on a manufacturing license that does require quota.

Q. Okay. And is that also what you meant when you said when you start needing quota, is that this research versus manufacturing distinction?

A. No, when we start needing quota is when the current quota is not sufficient for our demand plan and we need to ask for more quota, reviewing the market demand, the -- what's needed, and how much we have will last us.

Q. Describe for me generally how the quota process works from your perspective. The DEA provides a quota allocation for the Hobart manufacturing facility from time to time, correct?

A. Yes. We have an initial grant, and

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then if that initial grant is not enough to support, get you through the full calendar year, you can ask for more quota throughout the year.

Q. Okay. And so that initial grant is granted with respect to an upcoming calendar year?

A. Yes, it's applied for on April 12th of the preceding year, so we take -- for example, this April 1st coming up we will take our supply plan for 2020 of what's needed in the market and convert that into API, so how much API we need, and then that will be applied for with DEA by April 1st for 2020.

Q. Okay. And then the DEA acts on that application at some point prior to the upcoming January 1, provides the quota allocation for the upcoming calendar year, correct?

A. Yes.

Q. And so the quota allocation -- when you say API, I mean, that's active pharmaceutical ingredient, correct?

A. Yes.

Q. And so is the quota for -- that the DEA grants for the upcoming year, is that on an

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API by API basis?

A. Yes.

Q. And is it --

A. By molecule.

Q. By molecule.

Okay. So it isn't with respect to a particular dosage, for example, is that right?

A. I don't understand what you mean.

Q. So, for example, would you have a certain allocation of oxycodone for the calendar year as compared to an allocation of 20-milligram tablets, 30-milligram tablets, etcetera?

A. Yes, your application is submitted by dosage form.

Q. Okay. So for each API, the API is then broken down to -- in different dosages?

A. Yes.

Q. And that's how, ultimately the DEA when they grant the quota, that's how it's granted?

A. I don't know what formula DEA uses to grant it. We fill our application, and we tell DEA what we want and what we're going to make

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with it. Very, very seldom do we get a 100 percent grant.
Q. Okay. But whatever grant you get, it is expressed in terms of by API by dosage?
A. When we are given the grant we are given just the total API, so we apply for it specifying the dosage, but when the grant comes there's no dosage specified, and if they haven't given us 100 percent we don't know what they're expecting us to make with it.
Q. Okay. So let's just use oxycodone for an example, that's an API, correct, oxycodone?
A. Yes.
Q. Okay. And so when you submit the application, you would have that broken down in various dosages?
A. Yes.
Q. And a certain number of tablets in each dosage, correct?
A. Yes.
Q. And you could add up how many molecules are in all those tablets and then come up with a gross amount of oxycodone API that's covered by your application, correct?

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A. That's what the application amount was for, what all those dosage units compile total.
Q. Okay. But then when the DEA actually grants the quota, it's simply an amount of that API?
A. Yes.
Q. Okay. And so -- and that grant, as you indicated, may -- or frequently is less than the gross amount that was applied for, correct?
A. Correct.
Q. And so when that happens, do you have an understanding once you have that quota grant and, let's say, it's less than the gross amount that was applied for, what that -- what the Hobart facility is permitted to then manufacture in terms of different dosages under that quota grant?
A. So the business will decide based on the demand plan and the market demand what we'll make with the quota that we've been granted.
Q. Okay. And so is there any need to go back to the DEA for any further update on the quota or clarification once you make the determination of what to manufacture in light of

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the quota that was granted?
A. No.
MR. GOTTO: Okay. Why don't we take a short break. We've been going for over an hour.
THE VIDEOGRAPHER: The time is 10:13 a.m., and we're off the record.
(Whereupon, a recess was taken.)
THE VIDEOGRAPHER: The time is 10:31 a.m., and we're on the record.
BY MR. GOTTO:
Q. Ms. Spaulding, before we broke we were -- you were testifying about the quota process and some aspects of it. And if I understand correctly, from time to time there can be applications for an update to the quota during the calendar year, is that correct?
A. An increase, yes, we can request an increase at any time.
Q. And is that a process that you're involved in?
A. What time frame?
Q. Well, have you been involved in it at any time frame since you've been at Mallinckrodt?

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A. Yes.
Q. Okay. And what's been your involvement in that process?
A. As we discussed earlier, began as a second set of eyes, then took on additional responsibilities, and now currently I oversee the person who compiles them, and I review them before submission.
Q. Okay. In your experience, is it -- what's the frequency with which there are -- Mallinckrodt with respect to the Hobart facility has made application for increase in quota?
A. Depends on the molecule. Some molecules we get enough for our demand, and some molecules we have to ask. Depends on the market and disruptions. If another manufacturer is out of supply, the distributors could be attempting to get for us, so we're going to consume our quota faster than anticipated. There's many different factors.
Q. Okay. Is it -- has it ever been your experience since you've been at Mallinckrodt that with respect to -- well, strike that.
When you have worked on an application

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for a quota increase, what are the steps that go into that process?
A. We first take a look at what we've sold versus what we need to make for the rest of the year. We subtract out what we've been granted, and DEA has a formula that involves what you have on your end inventory, what you were granted, minus what you've sold in your forecast, and we will run those formulas to see if we have justification to have an increase for that calendar year. If a justification, meaning this formula, shows that we have a shortfall and that based on our sales we are entitled to more quota, then we will submit a request.
Q. Okay. And I think you testified before the break that it is sometimes the case that the quota that's granted for a calendar year is less than what was applied for, correct?
A. Yes, and many times it's less.
Q. Okay. And so if the quota -- let's say the quota was granted for less than what was applied for, and sales of that particular API are consistent with what the forecast had been, so as the year is unfolding, consistent with

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what your application originally showed, you'd be running short, correct, if the quota was less than what you applied for, correct?
A. Correct.
Q. And so in that situation, would you apply for increased quota?
A. Yes.
Q. Okay. So it could sometimes be the case that the application for increased quota could show sales consistent with what had previously been forecast, but the shortage arising from the fact that the quota that was granted was less than had been applied for?
A. Yes.
MR. O'CONNOR: Object to form.
BY MR. GOTTO:
Q. And then sometimes it may be the case that sales were actually greater than what had been forecast for one reason or another, and a shortage from the quota results, correct?
A. Yes.
Q. Okay. In your experience, what's the time frame approximately for the DEA to act on a request for increased quota?

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A. Currently?
Q. Sure, start with currently.
A. It's in the neighborhood of six to eight weeks.
Q. Okay. Has that changed over the years?
A. Yes. Several years ago it was in excess of 12 to 16 weeks, which is very difficult on the manufacturers because of lead times when we have to wait so long to get a quota grant, or to even know if we're going to get quota, to be able to plan our pipeline and our manufacturing, so when there was greater review within DEA and it could take four to six -- 14 to 16 weeks. Currently we're experiencing about six to eight weeks.
Q. And approximately what was the time frame when the longer time period applied?
A. I don't remember the years, but it was when Joe Rannazzisi was head of DEA and was reviewing and signing all quota requests.
Q. Okay. So it was your understanding there was a period of time when the actual head of the DEA personally reviewed and signed off on

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each quota request?
A. Yes.
Q. And do you know currently what the -- who at the DEA reviews and signs off on quota requests?
A. No, I don't.
MR. GOTTO: Can we go off the record one second?
THE VIDEOGRAPHER: The time is 10:37 a.m., and we're off the record.
(Pause.)
THE VIDEOGRAPHER: The time is 10:38 a.m., and we're on the record.
BY MR. GOTTO:
Q. So, Ms. Spaulding, when -- currently when there's a request for a quota increase, is that typically made as to one specific API?
A. Each quota request is by molecule.
Q. Okay. And is there, in your experience, is there a process of any sort of interaction with the DEA when the quota request is made? Is there back and forth with the DEA, or do you simply wait for them to act on it and see what they do?

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MR. O'CONNOR: Object to form.
A. Sometimes, sometimes, most commonly we just have to wait until we receive a letter. But if DEA wants additional information, like who we're selling to or detailed sales information, they'll e-mail us and ask for whatever additional information they want for use in reviewing our request.
BY MR. GOTTO:
Q. Okay. And is it your experience that generally do they ask for more information, or is that kind of an exceptional circumstance when they do that?
A. It's an exception to the rule.
Q. With respect to the Hobart manufacturing quota, who is it at Mallinckrodt that's had primary responsibility for submitting the applications and any applications for increased quota?
A. Primary responsibility is Carrie Johnson. She makes the application in the database, and drafts the letters of which myself and Karen review prior to submitting.
Q. Okay. And who is it at Mallinckrodt

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that has the authority to determine the amount of quota that will be requested from time to time?
A. I'm not sure I understand. Who is signing the letters?
Q. Well, that would be -- one question would be who signs the letters, sure.
A. Carrie Johnson is the applicator, because we have log-ins with DEA, so as she's the person filling in the data using her log-in to DEA's database, she is the person that signs the letters.
Q. Okay. Does she have the authority to make the decision as to the amount of quota that will be requested of the DEA either in an annual request or request for increase?
A. No, they're all reviewed, and either Karen or myself would approve them.
Q. Okay. Do you have an authority to approved without Ms. Harper's authorization?
A. For routine requests such as the initial, which there's no extraordinary circumstances, yes. If there's anything unusual, extraordinary, any outlying factors,

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then Karen would be -- would review and approve.
Q. Okay. So the initial, when you say "the initial," you mean the calendar year requests that you described was due April 1st of each year?
A. Yes.
Q. And so what's the process that you go through to compile that annual request?
A. So my team will generate all of the forecast data for the next year, because that's all we have at that time for a future year's forecast, and number of bottles to be sold, and then convert that back to amount of API, and account for processing waste, samples, and then determine a number to meet the demand plan.
Q. Okay. And when you say your team, who is participating in that process?
A. Carrie is the primary person.
Q. And the time period during which you've had that responsibility for the annual quota request, what's that time period?
A. When Carrie started reporting to me in April of 2017.
Q. Okay. Prior to that time, who was

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performing the corresponding duties with respect to the annual requests?
A. Karen.
Q. And did you assist in that other than the second pair of eyes role that you described?
A. I was copied on e-mails and was informed, but I didn't approve.
Q. Okay. The sales -- I'm sorry. The forecast data that supports the quota request, how is that compiled?
A. It's provided to us by our corporate planning team.
Q. Okay. And I think you've already testified that it's often the case that the quota that's actually granted by the DEA is less than what's applied for, is that fair?
A. Yes.
Q. So would there -- would it be possible to factor that in when you make the application, right, apply for more than you think you might need on the expectation that the DEA is going to grant less than you asked for?
MR. O'CONNOR: Objection to form.
A. It's an estimate. It's not hard

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numbers of what we're going to produce because it's a projection.
BY MR. GOTTO:
Q. So is there any negative consequence of if you were to apply for -- if you were to receive quota that exceeded what you ultimately turn out to need during that year, is there any negative consequences to that?
MR. O'CONNOR: Objection to form.
A. I don't think I understand what you're asking.
BY MR. GOTTO:
Q. Okay. Well, you make your quota application for the year, and if you receive quota that's less than what you actually need, obviously there's a potential negative consequence there that you can't fill the orders that you get?
A. Right.
Q. And you have to update that and try to get an increase during the year, right? That's one scenario. Sounds like that's not an uncommon scenario, right?
A. It's not. If we have excess quota at

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the end of the year, we review as part of our annual process in September and October if we are going to have excess quota, and we'll relinquish to DEA and let them know that the market has changed, or we had a project we didn't need the quota for, or any number of things that we're going to have excess quota.
Now, quota factors in a year-end inventory because of timelines. If you don't get your next calendar year quota on January 1, you're going to be out of supply for two months if you have a product that takes eight weeks to make, so they allow you to have a year-ending inventory so that you have API to start producing to allow for continuous supply. So we'll find out how much we need for a year-ending inventory and what we need to meet our plan, and if we have excess we'll relinquish it to DEA.
Q. And does that happen frequently that you have excess quota as you're approaching the year end?
MR. O'CONNOR: Objection to form.
A. It happens occasionally. I wouldn't

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say frequently. Depends on the molecule.
BY MR. GOTTO:
Q. And apart from this year-end straddling you described where they allow you to have a certain amount to keep your production straddling the year-end, is there any carryover from year to year of unused quota from one year to the next?
A. No, absolutely not. It has to be consumed by 12/31. The API has to be at your facility. If it's not at your facility on 12/31, it's use it or lose it.
Q. Going back to your -- earlier today you gave me a description of how your responsibilities evolved over the years, and we've been talking about the quota component of that. You indicated that at some point you became a compliance analyst, correct?
A. Yes, but it was a title. It wasn't -- I wasn't really an analyst. That was under the Tyco days, and they only had certain job descriptions, so I was the only one in the company who did what I did. They didn't really have a job title for controlled substances

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compliance associate or coordinator, so I was assigned a job title of analyst because that's where I fit within their career band.
Q. Okay. So that was pre-'07, then, if that was during the Tyco time?
A. Yeah, roughly. I don't remember exactly, but...
Q. And then after Mallinckrodt spun off from Tyco, what -- did you keep the compliance analyst title at that point?
A. Under Covidien I believe I was.
Q. And I've seen some documents where I think you signed as a compliance investigator. Did you have that title at some point?
A. That was the initial role in 2001. I was hired as a compliance investigator. Again, it was a title. I would investigate losses in transit, but I had many responsibilities.
Q. Okay. And then you indicated at some point you became the senior controlled substance compliance coordinator?
A. Yes.
Q. When was that?
A. I don't remember exactly when.

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Q. Do you have an approximate?
A. Before I was manager.
Q. Okay.
A. Sorry, I don't.
Q. And when did you become manager?
A. That, I remember, was April of 2017.
Q. Okay. But in terms of title, it was compliance analyst and then compliance coordinator and then ultimately manager, is that fair?
A. Yes.
Q. Okay. Now, you indicated one of the things you had responsibility for are DEA audits?
A. Yes.
Q. Tell me what the DEA audit process is that you had responsibility with respect to.
A. So when DEA came on-site to conduct an inspection, there's point of contacts that interact with the DEA, so there was -- it was typically myself and the security manager at the time were the two main points of contact with the DEA that facilitated the audit, so we would be in the front room with the DEA as they were

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doing their inspection, and they'd ask us for records, and we would go to our teams and get the records and bring them back. So we were considered the audit leads.
Q. Okay. And who were the persons who were in the role of security manager from time to time?
A. Rich Nikolaus prior to 2015, I believe, and currently Edward Egan.
Q. Any other roles with respect to the DEA audits apart from this process you described of retrieving records that were requested by DEA?
A. So I answered all of their questions in regards to our processes in the plant, how we handle -- facilitated the reconciliation, provided them with reports. Anytime that DEA came on-site, I was the point of contact. Whether it was for an inspection or to approve a cage or a vault or to do any type of anything on the site, I was the point of contact.
Q. Okay. Does this go back to 2001 that you were the point of contact for DEA visits?
A. 2001 I was what we call the back room,

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so I was the person pulling the records. Elizabeth McPhail would have been the front room person. And then after I started reporting to the materials manager, I became the front room person because Elizabeth McPhail was pulled out of the DEA role and I became the lead.
Q. Was there a reason for that change?
A. Not that I can remember specifically.
Q. Do you remember approximate time frame when that occurred?
A. Not exactly, no.
Q. So in terms of responding to questions that the DEA would pose during these audits, what sorts of questions can you recall the DEA posing to you?
A. Pretty standard audit questions, who do you use for your carrier, what is your business hours of operation, how many employees do you have, your power of attorneys, who can sign 222 forms. They have a binder of 66 questions that are all specific to that license that they're auditing.
Q. Okay. And were they typically things that you would be able to answer off the top of

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your head, or normally are they things that you needed to go back and research?
A. Most of the time I could answer them. I knew the processes, the plant inside and out and could answer most of their questions. If I couldn't, I didn't guess or speculate. I'd tell them I'd get the answer and get back to them.
Q. And the DEA audit, is it a regularly scheduled event with a regular frequency, or was it just whenever they happen to tell you they're going to do it?
A. They're typical actually unannounced, so it's whenever DEA shows up at our door. We need to be ever constantly ready for the DEA audit at any time, which we are.
Q. Is it ordinarily done -- even though it may be unannounced, is it approximately an annual event, or is it done more frequently than that?
A. The past audits have no rhyme or reason to any type of frequency.
Q. Does the DEA after their audit provide you with any sort of report or their feedback as to the results of the audit?

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A. There's never a DEA report. If they have concerns, they will discuss them with you at the time of the audit. They may direct us -- they may ask us a process, and I explain it, and they go, yeah, we're not comfortable with that, we want you to do it this way. And so we always do whatever DEA directs us because they have jurisdiction over us.

Q. Can you recall specific examples of any sort of negative feedback you got from the DEA as to a process or other matter that came up in the course of their audit?

MR. O'CONNOR: Objection to form.

A. A negative, I'd say no. They, you know, may, well, we don't really like that, or we think you should do it this way, or it will make it -- you know, if you give us a report in this format it makes it easier for us to reconcile.

Negative, I don't -- I don't know what would be considered negative. Any feedback they gave us was always constructive.

Q. Sure. Maybe negative is a bad word.

For example, you said they might from

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time to time say, well, we don't really like that, do it this way. Can you think of specific examples where that sort of comment came back to you?

A. We would stage material in our manufacturing hallway if it was getting ready to go into production within a day, and they said, well, we don't really like that, we'll let you stage it for up to a shift, so then we immediately changed all our processes that said we couldn't stage material for any longer than a shift.

Q. Anything else of that nature you can recall?

A. We wanted to store material from our manufacturing license in our distributor vault, and they said, no, they wanted us to write for a waiver. We couldn't -- it was -- it's in the regulations that we could do it, but they asked us to get a waiver on file, so we wrote for a waiver on file.

Q. You mentioned one of the topics that you have attended trainings on is state licensing?

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A. Yes.

Q. So in what aspects of state licensing did you have responsibility for from time to time at Mallinckrodt?

A. I don't have any responsibility for state licensing. I'm aware of it. I'd go to the trainings so that we're aware of any states that require us to report losses, or some states have additional reporting requirements, so we would attend the training to make sure we're aware of any individual state requirements --

Q. Okay.

A. -- that may impact the site.

Q. When you say "we," who else from Mallinckrodt attends those types of trainings?

A. It depends. So Karen Harper, my manager/director will attend, and Dave Hunter and myself will swap out. So we all can't leave all at the same time, there's got to be somebody at home, so we alternate and we'll take turns at conferences. That's why, for example, when I said the IQVIA conferences, you know, a half dozen because we alternate years of who attends.

Q. And how about, you indicated exports

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was another topic that you attend trainings on from time to time. What aspect of exports do you have responsibility for?

A. That I do have responsibility for applying for the 161 application to export our products, so I get the import permit from our customer service department who liaisons with our international customers, and then I file for the export permit. When the expert permit is received, I notify distribution and customer service that the order can be released, we have the permits.

Q. And you indicated the suspicious order monitoring was one of the topics that you attended trainings on. What aspects of suspicious order monitoring do you have responsibility for?

A. Currently that is done by my group. I have a data analyst auditor that reports to me, and she is the primary contact for part of our suspicious order monitoring program and our anti-diversion program. She does the daily orders review.

Q. And who is that?

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A. Rachelle Rogers currently.
Q. And what is the aspect of the SOM program that your team has responsibility for?
A. So we review the orders that are held for review that meet the algorithm criteria, we do Google searches, we do chargeback reviews, we respond to the DEA for shipping history verifications, we're in the process of transitioning the customer checklists to Hobart, off the top of my head.
Q. That customer checklist transitioning, what -- it's being transitioned from where?
A. It's currently residing with the -- our customer data integrity group, and we're going to be reviewing them in Hobart as opposed to out at corporate.
Q. And for how long has your team had these responsibilities with respect to SOM?
A. Since April of 2017.
Q. So before that time, what responsibilities did you have with respect to SOM?
A. I was a backup reviewer to the auditor analyst who was located in St. Louis, and I was

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a member of the SOM team.
Q. As a backup reviewer, what was your role there?
A. So if the primary reviewer was on vacation or out of the office, then I would conduct -- excuse me, I would conduct the daily reviews.
Q. And what do those reviews consist of?
A. Orders that have gone -- orders that have met the algorithm hit and have gone on hold, to review and determine if they're appropriate to release.
Q. And when did you first have that backup responsibility?
A. Roughly 2012.
Q. And you've made reference a couple times to the algorithm hit. When was the algorithm implemented, do you recall?
A. There's always been an algorithm in place since I went into the role. We've constantly enhanced the algorithm. But the exact formula of it, I don't remember the specifics.
Q. And when you say since you went into

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the role, what do you mean by that?
A. So when the distribution center was in St. Louis, they had a program in place, and when it moved to Hobart in 2001 that program transferred over to Hobart.
Q. Okay. So there was an algorithm in place from 2001 at Hobart for SOM?
A. To the best of my knowledge, yes.
Q. Do you recall what that algorithm consisted of in any regard going back to 2001?
A. I know it had something to do with sales history, but I don't remember the exact formula.
Q. Did you have an understanding of how the algorithm changed over time?
A. Not really, not until I was involved in it in 2012.
Q. So since 2012, has the algorithm changed?
A. Yes.
Q. And have you had an understanding of how it has changed since then?
A. Yes.
Q. And what -- tell me what you can

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recall as to how it's changed since 2012.
A. Since 2012, we were initially looking at 18-month history based on the bill to, and now we're looking at the 18-month history based on the ship to.
Q. And so tell me what the difference is between bill to and ship to.
A. So bill to is -- a parent company is where the bills go to, but they may have distribution centers all throughout the United States, and that's the ship to. So we bill to one location but we physically ship to another location.
Q. Okay. Any other changes in the algorithm since 2012 that you're aware of?
A. Not that I personally am aware of. But it was overseen by corporate, so I don't know if they may have been making changes to it or not.
Q. Do you have any understanding as to the reason for the change from bill to to ship to?
A. Just to always make it better and thought it would be an improvement.

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Q. You indicated that you've been a member of the SOM team. For how long have you been a member of the SOM team?
A. Well, I started doing the backup reviews in 2012, but I don't think I was part of the team until '14 or '15, right around there.
Q. So is the -- was the change to the algorithm that you described something that the SOM team had involvement on?
A. Yes.
Q. Were you involved in discussions of that change?
A. Yes.
Q. And what can you recall of those discussions?
A. Just that we thought it would be better to see the individual distributors versus the parent company to see the amounts going to individual distributors for analysis purposes.
Q. And do you recall why it was thought that that would be better?
A. Initially we thought that looking at the parent company as a whole would be better, because then if a distributor was shuffling

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between their distributions we wouldn't see it if we were looking at individual distributor, but by going -- looking at each distributor, then we could see what we were directly shipping to each location.
Q. You indicated that your team currently has at least some responsibility for the anti-diversion program?
A. Yes.
Q. And what are the responsibilities related to the anti-diversion program?
A. So we answer any DEA or law enforcement requests for shipping history information through our global security director. We receive -- I may receive a request from a law enforcement agency for placebo tablets for them to use in investigations, and I will facilitate that through the global security vice president. Anything that we can do to help battle diversion if we're asked upon it. We keep up-to-date with trends so that we have knowledge and aware of what's being abused so that we can pay particular attention to any specific molecule, drugs of concern. We sponsor

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drug take-back boxes in our local communities for the community to take back the unwanted medicines. It's a comprehensive program. We have disposal pouches that our government regulatory affairs department has provided to pharmacies and customers for people to dispose of unwanted opioids.
Q. To your knowledge, is there someone at Mallinckrodt that has responsibility for the overall comprehensive anti-diversion program?
A. We all have components of it. It's made up of different departments. I guess the overarching would be legal, corporate legal.
Q. And when you use the word "diversion," what do you mean by that?
A. Something taken out of the lifecycle in the hands of where it doesn't belong.
Q. When you say "lifecycle," what do you mean?
A. So we use the term analogy inside of the plant where if it's not in the lifecycle, so if it's not in the process of dispensing, blending, compression or packaging, it's out of the lifecycle.

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Q. So that lifecycle that you've described, dispensing, blending, compression or packaging, are those all things that occur in the plant?
A. Yes.
Q. Okay. So is diversion something that occurs in the manufacturing process, as you use the term?
A. There's potential. We have to maintain effective controls to detect diversion.
Q. And what controls are in place in terms of diversion in the manufacturing process?
A. There's many different controls, security systems, physical securities, tamper-evident bags, seals, two-person verifications. Every department has individual procedures based on their exposure and processing step.
Q. Okay. And then is there diversion that can occur after the product leaves the manufacturing facility?
A. Out of our hands?
Q. Yes.
A. I would say yes, there's a lot of

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opportunity for that.
Q. Okay. And some of the anti-diversion steps that you described, for example placebo tablets, to law enforcement, that would be related to diversion that's occurring after the product leaves your manufacturing facility, right?
A. Yes.
Q. And so diversion in that sense after it's left the manufacturing facility, when you use the term diversion in that context, what does it mean to you?
A. Not where it belongs.
Q. And you're aware that the litigation -- I realize you haven't read any of the operative complaints, but you're aware that the litigation in large part pertains to various opioids that have, to use your term, wound up not where they belong, correct?
A. Yes.
Q. And you're aware that that's become a serious problem over the last period of time, correct?
MR. O'CONNOR: Objection to form.

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A. Yes.
BY MR. GOTTO:
Q. When do you recall first being aware that the diversion of opioids was a serious problem?
MR. O'CONNOR: Objection to form.
A. I don't remember exactly when I -- when it started occurring to me.
BY MR. GOTTO:
Q. Okay. When you -- in 2001 when you first had responsibility in compliance, did you view diversion of opioids at that point as a serious problem?
MR. O'CONNOR: Same objection.
A. In 2001?
BY MR. GOTTO:
Q. Uh-huh.
A. No, I wasn't aware of it at that time.
Q. How about in 2012 when you indicated you became a member of the SOM team, at that point did you view diversion as a serious problem?
MR. O'CONNOR: Objection.
A. I don't recall if I did or not in

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2012.
BY MR. GOTTO:
Q. Do you recall any time at Mallinckrodt receiving any -- well, during the period that you reported to Ms. Harper, was there any -- ever a time when Ms. Harper communicated to you that -- a belief that diversion was a serious problem?
MR. O'CONNOR: Objection to form.
A. She may have. I don't remember any specifically.
BY MR. GOTTO:
Q. Okay. Do you recall anyone else at Mallinckrodt at any point communicating to you a belief that diversion was a serious problem?
MR. O'CONNOR: Objection to form.
A. I remember potentially Bill Ratliff, who was the security director at the time, raising the concern.
BY MR. GOTTO:
Q. Okay. In what context can you recall that?
A. Not specifics.
Q. Do you recall the approximate time

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frame?
A. No. There was a lot going on.
Q. You indicated that Mallinckrodt has a comprehensive program to try to address diversion, correct?
A. Yes.
Q. And so let's just talk about some of the components of that. One of them you indicated was providing placebo tablets to law enforcement, correct?
A. Yes.
Q. And do you recall when that began?
A. Approximately 2016.
Q. And you indicated that one of the things that's done with respect to diversion is to keep up-to-date on what the drugs of concern are, correct?
A. Yes.
Q. And I take it in that sense you mean concern to law enforcement?
A. Yes, and to DEA. DEA uses the terminology drugs of concern.
Q. Okay. And do you do anything personally to stay up-to-date on what the drugs

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of concern are?
A. I read the DEA's web page frequently. The auditor analyst in our team does social media reviews. We benchmark amongst our team members between Webster group, St. Louis, and Hobart. If somebody sees an article that's of concern, they'll share that article so that we can keep up-to-date with what's going on.
Q. Okay. And this process of being up-to-date on drugs of concern, when did that begin, at least as far as your own involvement in it?
A. With the DEA conferences, that's where we would hear that terminology, and they'd say they're paying particular attention to hydrocodone because it's a drug of concern. That was a comment when the quota reviews were taking an extended amount of time, industry was asking DEA why it's taking so long, and they said they were paying particular attention to drugs of concern.
Q. And when you're aware of a drug being identified as a drug of concern from time to time, what steps would that trigger at

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Mallinckrodt with respect to that particular drug?
A. Nothing different. We would still do all of our same processes that we always have done, it's just we were more responsive to a molecule that may be more susceptible to diversion.
Q. So more sensitive to it, but how does that sensitivity manifest itself in any particular action?
A. We may escalate quicker if we see a problem, or if I get a call from a law enforcement and they've expressed that they had a drug bust and it was of oxycodone, I would make sure that our security director and global VP were aware of it so that they could reach out and assist to the best of our ability.
Q. So what drugs can you recall being identified as drugs of concern? You've already mentioned hydrocodone. What other ones can you recall?
A. Hydrocodone, oxycodone. When DEA rescheduled hydrocodone from a C3 to a C2, they had said at one of their conferences that they

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were concerned about Codeine because that would remain a 3, and they were concerned that that would start replacing the hydrocodone. Most recent conference a couple years ago, they said hydromorphine 8-milligram was starting to be abused.
Q. And so the drugs that you can recall being identified as drugs of concern, were they all drugs that Mallinckrodt manufactured?
A. Yes.
Q. And were they all drugs that Mallinckrodt had a significant market share at least of generics?
MR. O'CONNOR: Objection to form.
A. I don't know, have any details on market share.
BY MR. GOTTO:
Q. Okay. Were you aware from time to time that Mallinckrodt was a leading manufacturer of many of the opioid drugs of concern that were identified from time to time?
MR. O'CONNOR: Objection to form.
A. No specific details. I had heard, you know, our site director refer to us as being one

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of the top manufacturers, but I didn't have firsthand knowledge of that.
BY MR. GOTTO:
Q. You've heard reference to an opioid epidemic in this country, correct?
A. Yes.
Q. When do you first recall being aware that there was an opioid epidemic?
MR. O'CONNOR: Objection to form.
A. I don't remember the exact time frame.
BY MR. GOTTO:
Q. Is it something that you can recall receiving any information from others at Mallinckrodt about?
A. No.
Q. You'd agree that certain prescription opioids manufactured by Mallinckrodt have been diverted over the years, wouldn't you?
MR. O'CONNOR: Objection to form.
A. Yes.
BY MR. GOTTO:
Q. And you would agree that certain opioids manufactured by Mallinckrodt have contributed to the opioid epidemic, wouldn't

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you?
MR. O'CONNOR: Objection to form.
A. I don't know that.
BY MR. GOTTO:
Q. You indicated that one of the -- one of your responsibilities has been to learn about applicable regulations that apply to the Hobart facility's manufacturing and distribution licenses, correct?
A. Yes.
Q. And do those include requirements to design and maintain a suspicious order monitoring program?
A. Yes.
Q. And so when did you first become familiar with those regulatory requirements?
A. So I knew that there was a system in place that was being reviewed out at corporate in the early 2000s, and then I recall the letters to industry as calling it out specifically.
Q. The letters from Mr. Rannazzisi?
A. Yes, from DEA.
Q. Did you receive those letters when

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they went out?
A. We received two of them. There was a third one that we didn't receive, like corporate had it from some avenue.
Q. Okay. So you were aware of corporate review in the early 2000s. In terms of your -- any personal involvement you had or responsibility that pertained to Mallinckrodt's regulatory obligation to design and maintain an effective SOM program, when did you first have any personal responsibility in that regard?
A. So a transition between Hobart and corporate a few times. There was a period, I don't remember the exact years, early 2000s, of which I would review the orders that were algorithm hits, and if need be get additional information through customer service. And then there was a point in time where it had transitioned back to corporate and was being reviewed at the corporate level.
Q. So when you -- during the period of time when you had responsibility to review the orders that were algorithm hits, any approximation what that time period is?

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A. No, just the early 2000s. I wouldn't want to guess. I can't remember exactly.
Q. All right. What would you do when there was an algorithm hit that -- you indicated you would review it through customer service. What were the specific steps you would take?
MR. O'CONNOR: Objection to form.
A. So if the order was -- on the list was a clinic, and it was a higher than -- order than they had been ordering historically, I would contact customer service, because they had the contacts with the customer, and say can you find out why this customer has ordered X number of bottles. And very commonly they would come back and they would say, well, the customer is moving and they ordered a double order to get them through until they get to their new location and their new 222 forms, or they were part of a chain and one of their other sister clinics closed so they were taking on those patients. And then I would write on the list of why, and I'd file it.
Q. When you use the term "algorithm hit," are you familiar with the term "peculiar order"?

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A. I've heard of that before.
Q. Okay. Was that a term that was part of the Mallinckrodt SOM process at some point?
A. Yes.
Q. And so was an algorithm hit, as you've used that term, the same thing as an order that was identified as a peculiar order?
A. Could be, yes.
Q. And so if an algorithm hit order was provided to you, or you became aware of it for SOM purposes, and you went through customer service and got an explanation and you noted what that explanation was, what would happen after that with respect to that particular order?
A. It would be released.
Q. It would be filled?
A. No. I apologize. So at that time these were excessive order reports, so it had already been shipped, and I was reviewing the orders after they had been shipped.
Q. Okay. So what would happen? Would anything happen after that, once you got the response back from customer service and you

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noted whatever the response was that you received? Would anything further happen with that order?
A. Those reports were sent to DEA. With that order, no, nothing further would happen with that order.
Q. Okay. But the -- there was a report sent to the DEA?
A. Mm-hmm.
Q. And what was the nature of that report? Was it a regular monthly report, or was it a particular report with respect to each order?
MR. O'CONNOR: Objection to form.
A. I don't remember if it was monthly or quarterly, but it was a PDF that was sent to DEA and what DEA classified and categorized as excessive order reports.
BY MR. GOTTO:
Q. Okay. And was -- were you the person who submitted those reports to DEA?
A. Yes, at that time.
Q. And again, do you have a time frame in mind when this was the applicable procedure?

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A. No. I remember doing it early in my career, and then it was transferred out to St. Louis, out to corporate, and I -- that's why I say early 2000s. It was the early part of my career, but I don't remember the exact time.
Q. Okay. So --
A. May I be excused?
Q. Yes.
MR. GOTTO: Let's go off the record.
THE VIDEOGRAPHER: The time is 11:26 a.m., and we're off the record.
(Whereupon, a recess was taken.)
THE VIDEOGRAPHER: The time is 11:40 a.m., and we're on the record.
(Whereupon, Mallinckrodt-Spaulding-1 was marked for identification.)
BY MR. GOTTO:
Q. Ms. Spaulding, we've handed you a document that we marked as Exhibit 1 bearing Bates MNK-T1_0000278740, appears to be an e-mail from Karen Harper to you dated 11/11/09 concerning your goal.
Would you please take a moment to look at that e-mail?

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A. Okay.
Q. Do you recognize that e-mail?
A. No.
Q. Did you annually establish goals that you would -- you and Ms. Harper establish what your goals would be for the upcoming year?
A. Yes.
Q. Any reason to think that this e-mail does not accurately describe what your goals are for 2010?
A. No.
Q. Okay. And among those goals, you'll see it indicates "Continue implementation and ongoing upgrades of the Suspicious Order Monitoring Program by second quarter fiscal year '10"?
A. Yes.
Q. And the fiscal here at Mallinckrodt ends when?
A. At this time our fiscal year was October 1 through September 30 -- 30.
Q. Okay. So the fiscal year 2010 would be the year ending September 30, 2010?
A. Yes.

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Q. And so the second quarter of that year would have been ending on March 31, 2010, is that right?
A. Yes.
Q. Do you recall what the implementation and ongoing upgrades tasks were that you -- that your goal included for fiscal year 2010?
A. No.
Q. Fair to say that at this point you would have had an understanding of at least some aspects of the SOM program at this time, correct?
A. Some aspects, yes.
Q. Had you had responsibility for implementation for upgrade of any aspect of the SOM program for fiscal year 2009?
A. I don't remember.
Q. And do you have any recollection of upgrades that you were involved in considering in fiscal year 2010?
A. No, not any specifics.
Q. Do you have any recollection as to any aspects of the SOM program that Ms. Harper indicated to you required upgrading in this time

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frame?
MR. O'CONNOR: Objection to form.
A. Can you restate that, please?
BY MR. GOTTO:
Q. Yes.
Do you have any recollection of Ms. Harper in this time frame indicating to you that there were any particular aspects of the SOM program that required upgrading?
A. I don't remember the specifics, no.
Q. Do you have a general understanding of what required upgrading?
A. No.
Q. Do you recall if there was a written SOM program at this point?
A. What do you mean by "written"?
Q. Well, was there a SOM program that was memorialized in any sort of document?
A. Oh, an SOP?
Q. Well, or any sort of document.
A. Not at this time. I don't remember what was in place at this time.
Q. Okay. You don't recall one way or the other whether there was a written program or

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not?
A. I don't.
Q. Do you recall working with anyone in fiscal year '10 on the implementation and upgrading of the SOM?
A. In fiscal year '10. I know there was a review of the program done. I don't know what year it was.
Q. Okay. Who can you recall being involved in that review?
A. Karen Harper.
Q. Anyone else?
A. There would have been other stakeholders of the business, but I don't remember the specific people.
Q. And you don't recall what the time frame was of that review?
A. No.
(Whereupon, Mallinckrodt-Spaulding-2 was marked for identification.)
BY MR. GOTTO:
Q. We've handed you what we've marked as Exhibit 2, a multi-page document beginning at MNK-T1_0000490704, appears to be a Fiscal Year

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'10 Assessment.
Would you take a look at that document and tell me if you recognize it?
(Witness reviewing document.)
A. This is my year-end review for fiscal year '10.
Q. Okay. Did you receive a similar review each year?
A. There's a review done each year, it's not -- it's a different software program, but yes, there's a review done each year.
Q. Okay. If you would turn to the page that's numbered 5, it ends in Bates 708. And the Performance Factor or Target Competency is "DEA Reports."
Do you see that?
A. Yes.
Q. Okay. And in the Expected Results paragraph, the last sentence says "Continue implementation and ongoing upgrades of the Suspicious Order Monitoring Program by second quarter fiscal year '10."
That's what we had seen in the prior document, correct, your goals for fiscal year

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'10?
A. Yes.
Q. Now, that was -- was that upgrade accomplished in fiscal year '10?
A. I don't remember what the upgrade was to know whether it was completed that year or not.
Q. So in your "End-of-Year Accomplishments (Employee)" paragraph, the last sentence indicates "Continuing to assist and implement upgrades on the SOM when identified along with generation of a quarterly report to DEA."
Do you see that?
A. No. I'm sorry. Which one? Under that same one?
Q. Sure. Yes, "End-of-year Results/Accomplishments (Employee)," the paragraph that begins "All controlled substance reports."
A. Okay. My -- that was my feedback. Okay. I'm sorry.
Q. It's the last sentence of that paragraph.

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A. Yes.
Q. Okay. And then if you look at the following paragraph "End-of-Year Results/Accomplishments (Manager)," would that have been Ms. Harper preparing that?
A. Yes. So the employee was my -- my review of my work throughout the year, and then the next one was Karen's, yes.
Q. Okay. And under the manager paragraph, the last sentence reads "Eileen volunteered for extra responsibility within the Suspicious Order Monitoring Program in fiscal year '10, enhancements to the system and expansion of Eileen's role will be accomplished in fiscal year '11."
Do you see that?
A. Yes.
Q. And so does that indicate that the -- whatever the upgrades were that were the subject of your goal for fiscal year '10 were not actually implemented in fiscal year '10, correct?
MR. O'CONNOR: Objection to form.
A. I don't know that.

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BY MR. GOTTO:
Q. Okay. Well, there's nothing either in your -- the employee end-of-year results/accomplishments or the manager end-of-year accomplishments that indicates that those upgrades were completed in 2010, correct?
A. Correct.
Q. And the manager comments indicate that there will be enhancements and expansion of your role accomplished in fiscal year '11 -- 2011, correct?
A. Yes.
Q. Do you recall what those enhancements to the system or expansion of your role were in 2011?
A. No.
Q. Under the paragraph -- the employee feedback paragraph, at the very end there's reference to quarterly report to the DEA.
Do you see that?
A. Yes.
Q. What was that quarterly report?
A. So that was the algorithm hits for each month combined by quarter and then

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submitted to DEA.
Q. And so was that a report you were submitting in fiscal year 2010?
A. I don't remember. "When identified along with generation of quarterly report."
Q. Well, you make reference under your accomplishments to generation of a quarterly report to DEA, correct?
A. Yes.
Q. And that quarterly report would be the algorithm hit or peculiar order hit report that you testified to earlier today, correct?
A. Yes.
Q. Do you know if any orders were identified as suspicious orders in fiscal year 2010 by Mallinckrodt?
A. No, I don't know.
Q. Can you recall at any time during your time at Mallinckrodt an order being reported to the DEA by Mallinckrodt as a suspicious order?
A. Yes.
Q. When can you recall that?
A. I don't know when it was for. I don't know when it was reported.

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Q. Do you recall any details about the order?
A. Yes, it was for fentanyl that was going to a veterinary clinic or a veterinarian.
Q. Okay. And was this a single incident?
A. That I was aware of. I don't -- there was others that were part of the program, and monitoring, they may have reported.
Q. Okay. As far as your own personal knowledge, you're only aware of the one, right?
A. Yes.
Q. And in terms of have you heard of others at Mallinckrodt -- other than things you've had personal involvement with, have you heard of other orders that Mallinckrodt reported to DEA as suspicious orders?
A. I don't recall.
Q. Okay.
(Whereupon, Mallinckrodt-Spaulding-3 was marked for identification.)
BY MR. GOTTO:
Q. We've marked as Exhibit 3 a two-page document bearing a Bates MNK-T1_000702654. Would you take a moment to look at those

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e-mails, please?
(Witness reviewing document.)
A. Okay.
Q. Do you recognize those e-mails?
A. No.
Q. Okay. These refer to a midyear assessment done in April of 2011, correct?
A. Yes.
Q. Was that a normal process at Mallinckrodt, that you would receive a midyear assessment of your performance?
A. Yes.
Q. Okay. The e-mail from Ms. Harper on April 7th of 2011 indicates that you took the lead in auditing Cedardale distributor after the program identified that customer as distributing excessive amounts of oxycodone into the State of Florida, correct?
A. Yes.
Q. And that you proofread and edited the three revised SOPs related to SOM, correct?
A. Yes.
Q. Do you recall the Cedardale audit that's referred to?

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A. Yes.
Q. What can you recall about that audit?
A. The security manager and myself went to Cedardale in New Jersey to perform an on-site audit of their -- it's more a collaboration visit just to review their SOM program.
Q. And what triggered that audit?
A. A report that Karen had in which she saw a high amount of oxycodone, or the team saw a high amount of oxycodone going into the State of Florida.
Q. Okay. And who was the security manager who performed that audit with you?
A. Rich Nikolaus.
Q. And I take it that was an on-site audit of Cedardale's facility?
A. Yes.
Q. Had you been to that facility previously?
A. No.
Q. Had you had any interaction with the people at Cedardale prior to your audit?
A. No.
Q. Was the audit scheduled, or did you

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just show up? How did it come to be?
A. It was scheduled.
Q. And how did you know what procedures to follow in conducting that audit?
A. So what our process was, or -- so we -- just through conducting audits, learning from DEA what were drugs of concern, we went and reviewed their SOM program.
Q. Okay. Well, let me back up.
Had you conducted other audits of distributors prior to this one?
A. No.
Q. Okay. And had you participated in any audits of distributors prior to this one?
A. I hadn't participated in on-site audits, no.
Q. Okay. So how did you know what to do as part of the audit if you hadn't done one before or participated in an on-site audit?
A. So we had -- we've had collaboration calls with distributors that I had been on, and had heard the questions that the compliance manager and the security director from corporate had been asking. We had a checklist that we

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used to prompt questions. We knew what our own program was at the time. We had gone to trainings and had -- from DEA and who had said from the pulpit that, for example, thresholds are not acceptable as a stand-alone SOM program, that's not an indicator of a good program if it's only based on threshold quantities.
Q. What does that mean, threshold quantities?
A. So a certain limit, they can order up to X amount, and then after that amount, say, per month, the first and the next month they could order that amount again.
Q. Okay. Were there particular concerns regarding Cedardale that you wanted to be sure you addressed as part of this audit?
A. Well, as a result of whatever the team had discovered, we were wanting to confirm if they did, in fact, have large amount of oxycodone going into Florida.
Q. Okay. And so what steps did you take to try to confirm that?
A. We just spoke to them. It was all reliable -- relied on them describing. We

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didn't review their records or their policies. We'd ask them if they had policies in place, but we didn't approve or condone or authorize an SOM program.

Q. Okay. Did you -- did they have a written SOM program that you reviewed?

A. Not that I can recall.

Q. But they described to you what their SOM program was?

A. Yes.

Q. And what can you recall the description?

A. That it was primarily based on these threshold quantities which DEA had said from the pulpit was not sufficient enough.

Q. Okay. And so when you can recall DEA saying that the threshold quantity approach was not sufficient, did they give any indication of what additional components an SOM program should contain beyond threshold quantities?

A. No. There's been very lack of guidance from DEA around suspicious order monitoring and what is good and what is not good. They would tell us things to be aware of

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such as red flags, but they wouldn't tell us what makes a good program or what doesn't make a good program, only to be aware of.

Q. Okay. So when you conducted the audit at Cedardale, their SOM program as they described it to you simply consisted of this kind of threshold quantity limit that DEA had specifically said was inadequate, is that fair?

A. Yes.

MR. O'CONNOR: Objection to form.

A. Yes.

BY MR. GOTTO:

Q. Okay. And did you tell them that, that your understanding from DEA was that that was not an adequate?

A. We did coach them in that they should have more around their program than just a threshold quantity amount, and that they should be looking at their pharmacies holistically in doing on-site inspections. It was a recommendation.

Q. When you say "looking at a pharmacy holistically," what do you mean by that?

A. Their amount of controls versus

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non-controls, their amount of cash versus non-cash, their demographics around the area to know whether the quantities that they're shipping to the pharmacy are justified or not.

Q. In the audit you did of Cedardale, did you take any steps to identify who any specific customers of Cedardale were?

A. I don't remember if we had specific names or not.

Q. I take it that the focus of the audit was this question of whether Cedardale was distributing excessive oxycodone to Florida, correct?

A. Yes, because we're concerned about our direct customers, and we were trying to make sure they had a robust program in place.

Q. Okay. At this time -- well, let me ask you, do you recall when the Cedardale audit was conducted?

A. Early 2011.

Q. Okay. At that time did you have any information with respect to the identity of any of Cedardale's customers?

A. I don't remember if I did or didn't.

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Q. Do you recall at any point seeing any reports of analysis of chargeback data that contained information with respect to the ultimate -- with respect to the customers of Mallinckrodt's customers in 2010 or 2011?

A. I remember that there was three customers that we as an SOM team decided that needed to be audited. I don't remember the specifics behind it.

Q. Okay. Do you remember who those three customers were?

A. Masters and KeySource in Cedardale.

Q. Do you recall seeing a report at any time in 2010 that identified customers who ordered controlled substances from multiple Mallinckrodt distributors?

A. No.

Q. Do you recall being aware of the existence of such a report?

A. Yes. I think there was something that prompted the team to review those three customers.

Q. And do you know if that report regarding customers that ordered from multiple

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Mallinckrodt distributors, do you know if that was generated through an analysis of chargeback data?
A. I don't. Don't remember.
Q. Do you know who Kate Mellencamp was, or Kate Neely? I think it was the same person.
A. Yeah, I remember the name. I don't remember the role.
Q. Okay. How about Ginger Collier?
A. Yes, Ginger I remember.
Q. And who was she?
A. She was in marketing.
Q. Do you recall if Ms. Collier or Ms. Mellencamp had any role in developing this report on multiple orders from multiple distributors?
MR. O'CONNOR: Objection to form.
A. I don't remember specifically anything.
BY MR. GOTTO:
Q. Okay. And so when you conducted the audit at Cedardale, were you aware of whether any of Cedardale's customers had been identified as parties who ordered from multiple

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Mallinckrodt distributors?
A. I don't remember anything about knowing their pharmacies, knowing who they were supplying.
Q. What was the -- what can you recall about the results of the Cedardale audit?
A. I remember that we were not comfortable that they had a robust enough program in place.
Q. Okay. And as a result, was Cedardale cut off from -- as a Mallinckrodt distributor?
A. I recall that they were -- we stopped shipping to them. I don't recall if it was before the audit or not, or a result of the audit.
Q. And do you know if Mallinckrodt ever resumed shipping to Cedardale after that?
A. I believe we did with some restrictions.
Q. Do you know what the restrictions were?
A. C3 through 5 only. We didn't resume shipping C2s.
Q. Exhibit 2 also indicates -- I'm sorry,

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3, not 2, 3 indicates that you proofread and edited the three revised SOPs related to SOM. And again, this is April, 2011. Do you recall those three revised SOPs?
A. Not which specific SOPs they are.
Q. Do you recall the subject matter of what was addressed in any of those -- by any of those revised SOPs?
A. Well, we have three SOPs that apply to suspicious order monitoring. I'm not sure that those are the three SOPs that we're talking about.
Q. So the SOPs that apply to SOM, what are the subject matters that they cover?
A. One, how to do the review of the algorithm hits. And I don't remember exactly what the other two are, not definitely.
Q. And when did these SOPs come into existence, as far as you know?
A. They were drafted by the SOM team and reviewed, so whenever that team took it back from Hobart and was reviewing the program. I don't remember. It was before 2011, obviously, but I don't remember when.

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Q. Okay.
(Whereupon, Mallinckrodt-Spaulding-4 was marked for identification.)
BY MR. GOTTO:
Q. We've marked as Exhibit 4 a multi-page document beginning at Bates MNK-T1_0007730928. Appears to be an e-mail thread from 2013 between you and Ms. Harper. Would you take a moment to look at that, and tell me if you recognize it.
(Witness reviewing document.)
Q. Feel free to look at whatever you want, my only question is on the first page of that document.
A. Okay.
(Witness reviewing document.)
Q. Do you recognize that document?
A. No, not exactly.
Q. Okay. On the first page, the e-mail from you to Ms. Harper, October of 2013, any reason to doubt that you sent this e-mail?
A. No.
Q. Okay. Under "Suspicious Order Monitoring" in the middle of the page, do you see that?

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A. Yes.
Q. "Description. Support Legal Department Regulatory Compliance in the arena of interaction with the Drug Enforcement Administration by managing and coordinating enhancements with the SOM program."
Do you see that?
A. Yes.
Q. Do you recall the enhancements to the SOM program that you managed or coordinated in this time frame?
A. No, we were always constantly trying to change it, make it better, so I don't remember what in specific.
Q. Okay. The next paragraph says "Ensure all orders placed on SOM hold are reviewed thoroughly and accurately to ensure SOM DEA Compliance."
In this time frame in 2013, who was involved in the review of orders that were placed on SOM hold?
A. Jen Buist, but I don't know when she came on board.
Q. And what department did she work in?

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A. She was under government compliance at that time.
Q. So was she the person who would review an order that was placed on hold to determine whether the order would be released?
A. Yes.
Q. And so in terms of your ensuring that orders were thoroughly and accurately reviewed, did you interact with her?
A. She -- if she was unsure of an order and wanted to know some supporting data, she would reach out to me. But I was the backup at this time. So it's referring to any order that I reviewed.
Q. Okay. But she had the ability to review and release an order without consulting with you, is that correct?
A. Yes.
Q. The next paragraph under "Employee Evaluation" says "Fiscal year '13 has been a challenging year for the Hobart site from the Controlled Substances Compliance aspect."
What can you recall that made fiscal year '13 a challenging year as you state in that

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sentence?
A. We had a very intensive DEA inspection that year.
Q. Okay. And what aspects of the inspection were particularly intensive, as you can recall?
A. Just there was many investigators there for six weeks.
Q. Did that investigation extend to any aspects of the SOM program?
A. Yes.
Q. In what regard can you recall them interacting with you with respect to SOM?
A. They were asking us about our SOM program in which we, as did any other audit, would explain the program at that time.
Q. Do you recall if DEA identified to you any shortcomings or criticisms of the SOM program?
A. Not that I remember.
(Whereupon, Mallinckrodt-Spaulding-5 was marked for identification.)
BY MR. GOTTO:
Q. We've marked as Exhibit 5 a two-page

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document beginning at Bates MNK-T1_0000274080, an e-mail dated -- well, series of e-mails dated May of 2008. Would you take a moment to look at those e-mails, please?
(Witness reviewing document.)
Q. Do you recognize those e-mails?
A. No.
Q. Okay. The May 12th e-mail from Ms. Harper indicates that she's gathered a group consisting of a few persons that she identifies to review the suspicious order monitoring program with the goal of making it more robust in light of DEA activity, and she asks if you would be willing to review a draft procedure and serve on the team as a Hobart advisor.
Do you see that?
A. Yes.
Q. And do you recall her making that request to you in 2008?
A. Based on -- only based on this e-mail. I don't recall it.
Q. All right. And then you respond "Absolutely - currently at DEA conference," correct?

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A. Yes.
Q. And no reason to doubt that you sent that e-mail, correct?
A. No.
Q. Okay. In Ms. Harper's e-mail under the dashed lines there are -- as an aside, she mentions in a conference she attended "among the agenda items was Suspicious Order Monitoring."
Do you see that?
A. Yes.
Q. And "Other suggestions included," she states, "On-site visits for all controlled substance customers; Close scrutiny of small, independent pharmacies; Close scrutiny of pain management clinics."
Are any of those three steps anything that you can recall being implemented at Mallinckrodt in this time frame in 2008?
A. In 2008, no.
Q. Do you recall when any of those steps were implemented at Mallinckrodt?
A. We started on-site visits of controlled substance customers in 2010, '11 with the KeySource, Masters, and Cedardale that we

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spoke of.
Q. Okay. In Ms. Harper's e-mail to you, she identifies a goal of making the SOM program more robust. Do you recall what the SOM program consisted of in May of 2008?
A. Not exactly, no.
Q. Do you have a general recollection?
A. Generally it was just the algorithm.
Q. And do you recall what the components of the algorithm were at this point?
A. Only one of them. That was based on their previous order history.
Q. Would that be the sort of threshold metric that you understood the DEA said was inadequate?
MR. O'CONNOR: Objection to form.
A. No. So a threshold is when you say, okay, they can only order up to 5,000 dosage units a month. This was based on what they historically had been ordering to know that -- whether they were continuing to order in historical patterns.
BY MR. GOTTO:
Q. So was it your understanding in 2008

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that the SOM program that was in place at Mallinckrodt complied with DEA requirements?
A. Based on the knowledge we had at that time, yes.
Q. Did there come a time when you had an understanding that the SOM program in place at Mallinckrodt did not comply with DEA requirements?
A. No.
(Whereupon, Mallinckrodt-Spaulding-6 was marked for identification.)
BY MR. GOTTO:
Q. Exhibit 6 is a lengthy document beginning at Bates MNK-T1_0005187729. It's an e-mail attaching a PowerPoint presentation, the first page of which contains your name.
It's a lengthy document, I can direct you to a few pages that I have some questions for you on rather than have you review the entire document. But certainly feel free to look at any part of it that you need to to answer any of my questions.
Do you recall what the purpose of this document was?

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A. Yes.
Q. What was it?
A. It's what we used for training new employees when they started.
Q. Okay. And just for the record, the cover e-mail is dated January of 2011, correct?
A. Yes.
Q. And did you prepare the portion of the presentation that's the slides that are behind your name?
A. It was a combination of Karen Harper and myself.
Q. Okay. If you turn to the page -- unfortunately these are not numbered. Let me just count pages for you, 1, 2, 3, 4, 5, 6, 7, the eighth page in, there's "Statistics on National Drug Abuse Trends."
Do you see that?
A. "DEA Regulatory Authority" up on the top?
Q. Well, it's immediately behind the slide that says "Security & Controlled Substance Compliance."
A. Oh, yes. Okay.

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Q. So there's "Statistics on National Drug Abuse Trends," and the following slide is "Abuse Trends." Why was it important to give this information to new hires in their training?
A. Because we wanted them to understand why we have these security policies and procedures around our processes, and why two people have to be present at all times.
Q. Okay. And so the page -- the slide, I think, the next one after the one you're on, there you go, "Abuse Trends," identifies certain statistical items such as "estimated 48 million people have used prescription drugs for non-medical reasons in their lifetimes." These abuse trends were something that Mallinckrodt tracked at the time, correct?
A. No. This is information that we gleaned off of either DEA's website or NIDDA's website.
Q. Okay. The following slide, "DEA reiterates responsibilities." Do you see that one?
A. Yes.
Q. And on this slide you make reference

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to certain statements made by DEA in correspondence to Mallinckrodt, correct?
A. Yes.
Q. Are these items of correspondence the -- two of the items you referred to earlier today in your testimony, letters from DEA?
A. The one letter is. I don't recall the one that was specific for Mark Coverly.
Q. Okay. The one on the right from Mr. Rannazzisi?
A. Yes.
Q. The following slide "Recent DEA Actions Involving Distributors" which talks about actions involving AmerisourceBergen, Cardinal, and McKesson, why was it important to provide that information to new hires?
A. Because we wanted them to understand the importance of having a DEA license.
Q. And then the following several slides involve specific examples, Masters Pharmaceutical, Rite Aid Issues, CVS Fines. Why was it important to provide that information to new hires?
A. To show them that DEA can take action

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against a registrant and their registration regardless of who you are.
Q. All right. You can put that aside.
(Whereupon, Mallinckrodt-Spaulding-7 was marked for identification.)
BY MR. GOTTO:
Q. We've marked as Exhibit 7 a multi-page document beginning at Bates MNK-T1_0000448773. It's entitled "oxycodone Extended Release Risk Map Action Plan." Let's take a look at that document, and tell me if you recognize it.
A. No.
Q. You don't recall ever seeing this before?
A. No, I don't remember it.
Q. Are you familiar with the -- with Mallinckrodt having a risk map action plan with respect to various products?
A. I'm aware that some products require risk map programs.
Q. Okay. And do you know which products require those programs?
A. Oxycodone ER was one of them. There's several others, but I don't know them

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specifically.
Q. And do you know why oxycodone requires a risk map action plan?
A. No, that's an FDA requirement.
Q. Do you know if Mallinckrodt had any other -- Mallinckrodt manufactured any other opioid other than oxycodone that required a risk map action plan?
A. Yes, there were others, but I don't remember specifically which products.
Q. Did you have any involvement in the preparation of the Oxycodone ER risk map action plan?
A. I don't remember it, so I'm not sure.
Q. Okay. If you turn to Page 3 of the document ending in Bates 775, under "Supply Chain & Security," you see your name appears on several of the entries.
Do you see that?
A. Yes.
Q. So one entry, "Provide notification to DEA of any confirmed diversion," and you're one of the persons responsible there, correct?
A. Yes.

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Q. Do you ever recall that occurring, that you provided notification to DEA of any confirmed diversion?
A. No, that would have been a 106 form.
Q. And do you recall ever providing a 106 form to DEA confirming diversion on oxycodone?
A. Oxycodone, or Oxycodone ER?
Q. Oxycodone ER, I'm sorry.
A. No, not without looking at my records.
Q. Next item is "Notify Covidien management...of suspected diversion."
Do you see that?
A. Yes.
Q. Do you recall ever doing that notification of Covidien management of suspected diversion of Oxycodone ER?
A. No, I don't remember.
Q. On the next page, Page 4, the -- one, two, three -- fourth item down, "Photographs of drivers authorized to handle controlled substances are maintained on file at the distribution center." Is that something that was done at Hobart?
A. Yes.

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Q. Three items down from there, "Audit carrier records annually." Your name is listed. Is that something that you participated in?
A. At that time, yes.
Q. Do you recall an individual named John Gillies?
A. Yes.
Q. What was his role?
A. He was not here at the time. This was -- Bill Ratliff was the security director. John Gillies is the vice president of global security.
Q. Currently?
A. Yes. John Gillies was Bill Ratliff's successor.
Q. Okay. So to the extent Mr. Ratliff is identified as having responsibilities on this risk map action plan, currently those would be Mr. Gillies responsibilities?
MR. O'CONNOR: Objection to form.
BY MR. GOTTO:
Q. As far as you know.
A. Yes. We don't have this product anymore.

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Q. Okay. Do you interact with Mr. Gillies?
A. Yes.
Q. In what capacities?
A. I escalate to him any law enforcement inquiries for either law information or the placebos as we talked about earlier, and if he contacts me for information, I provide it.
Q. Have you ever had any -- has Mr. Gillies ever expressed any dissatisfaction with your work product?
A. Not that I can recall.
Q. Have you had any difficulties in interacting with Mr. Gillies over the years?
A. No.
MR. GOTTO: Let's go off the record.
THE VIDEOGRAPHER: The time is 12:32 p.m., and we're off the record.
(Whereupon, a luncheon recess was taken.)

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AFTERNOON SESSION

THE VIDEOGRAPHER: The time is 1:15 p.m., and we're on the record.
BY MR. GOTTO:
Q. Welcome back, Ms. Spaulding.
A. Thank you.
Q. Before our lunch break you had testified about the one suspicious order you could recall, which I think was a fentanyl order that went to a vet clinic, is that correct?
A. Yes.
Q. Okay. You'd agree with me that if a vet clinic purchased opioids and then resold them to a human pain clinic or a human physician, that would be a potentially suspicious order, wouldn't it?
MR. O'CONNOR: Objection to form.
A. I wouldn't know if a vet clinic sold it to anybody else. We would only have the direct sales. And a vet clinic wouldn't apply with chargebacks.
BY MR. GOTTO:
Q. So you're not aware of any situations

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in which Mallinckrodt opioids were purchased by a veterinary supply company and then resold to medical clinics or dispensing physicians?
A. Not that I'm aware of.
Q. And do you know if Mallinckrodt's records would include that information if it had, in fact, occurred?
A. I don't know what our records -- that our records would include that.
Q. In any event, you've never heard of that happening?
A. Correct.
(Whereupon, Mallinckrodt-Spaulding-8 was marked for identification.)
BY MR. GOTTO:
Q. Just one last question on that one before you turn to that document.
If you were aware of that happening, that a veterinary supply company purchasing from Mallinckrodt had resold to a medical clinic or dispensing physician, would you have investigated that as a potentially suspicious order?
A. Yes, we would have raised that to the

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suspicious order monitoring team for evaluation.
Q. Okay. I've just handed you what we've marked as Exhibit 8, which is a single-page document bearing Bates MNK-T1_0006443249, an e-mail thread from 2005. Take a look at that for a moment, if you would, and tell me if you recognize it.
A. Okay.
Q. Do you recall those e-mails?
A. No.
Q. Okay. Do you know who Mike Spears was?
A. Yes.
Q. Who was he?
A. Director of what we call PPT, product process technology.
Q. And how about Laura Ashline?
A. She's a project manager.
Q. Okay. And Jim Walter?
A. He was the site director.
Q. Okay. Your e-mail to Mr. Spears and Ms. Ashline says "At the request of the DEA they would like to know the timeline for release of Oxycodone ER products (all strengths) into the

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marketplace as MS Contin is extremely abused and they want to know when we are going to start producing from this facility."
Do you recall DEA making that inquiry of you?
A. No.
Q. Okay. Do you recall being aware in 2005 that MS Contin was extremely abused?
A. Only based on this e-mail.
Q. Do you recall being aware in 2005 that Oxycodone ER would also have the potential to be abused?
A. Only based on this e-mail.
Q. And Mallinckrodt began manufacturing Oxycodone IR shortly after this, isn't that correct?
A. We were manufacturing -- which strength of IR?
Q. Well, in any strength.
A. So we had been manufacturing oxycodone 5-milligram prior to this. I don't remember when we started manufacturing oxycodone 15-milligram or 30-milligram IR.
Q. Okay. And Oxycodone IR also has the

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potential for abuse, correct?
A. Yes.
Q. And were you aware of that back in 2005?
A. I don't remember when I was aware of it.
Q. Okay. All right. You can set that aside.
(Whereupon, Mallinckrodt-Spaulding-9 was marked for identification.)
BY MR. GOTTO:
Q. We've marked as Exhibit 9 a two-page e-mail thread beginning at Bates MNK-T1_0000492214. Take a look at those e-mails, if you would, and tell me if you recognize them.
(Witness reviewing document.)
A. Yes.
Q. And do you recognize these as e-mails from April of 2007 involving you and Ms. Harper as well as some others concerning a suspension of AmerisourceBergen by FDA -- by DEA?
A. Yes.
Q. Do you recall that circumstance

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occurring?
A. Yes.
Q. And AmerisourceBergen was a large customer of Mallinckrodt, correct?
A. Yes.
Q. And they, according to this press report, they were temporarily suspended as a result of shipping to certain pharmacies in Florida, correct?
A. Based on this release, yes.
Q. And this is dated in 2007. Were there any steps taken in 2007 in light of this suspension of AmerisourceBergen to evaluate whether any AmerisourceBergen orders from Mallinckrodt were suspicious?
A. I don't remember if there was any specific steps.
Q. Was there an audit conducted of AmerisourceBergen?
MR. O'CONNOR: Objection to form.
A. Not that I was directly involved in.
BY MR. GOTTO:
Q. Were you aware of an audit being conducted of AmerisourceBergen at any time in

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the 2007 time frame?
A. No, not that I can recall.
Q. Or in 2008?
A. No.
Q. Or 2009?
A. No.
Q. Or 2010?
A. No.
Q. Now, in your e-mail, the second one on the first page of the exhibit, you note that AmerisourceBergen had already been reinstated by the DEA. How did you know that?
A. I don't remember how I knew back at that time.
Q. And Ms. Harper in her April 27th e-mail says "sometimes we are met with internal pushback and the attitude that we are 'such big players' that DEA would never suspend our license."
Do you see that?
A. Yes.
Q. Do you recall Ms. Harper expressing that sentiment to you, that sometimes that that attitude was expressed at Mallinckrodt?

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A. Yes.
Q. And did you ever hear anyone express that attitude?
A. There was internal pushback both ways, so they would push back on us and we would push back as well.
Q. And when you say "they" in that setting, who is the they?
A. Management, stakeholders in the business.
Q. And pushback on whom?
A. The compliance team.
Q. And what would the form of the pushback be?
A. If we wanted to purchase physical -- additional equipment for physical security to make us -- to enhance, but at all times it was -- we were always in compliance. It was always to make us better or to be able to look at things differently. At no time were we not compliant. If we were, we -- the business would have given us anything we needed to be compliant.
Q. So one form of pushback that you're

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recalling is where you may have made a request for some sort of enhancement to security and that request was rejected?
MR. O'CONNOR: Objection to form.
A. Was challenged.
BY MR. GOTTO:
Q. Do you remember any specific request in that regard?
A. Nothing specific.
Q. So the attitude that Ms. Harper is referring to is one that "we are 'such big players' that DEA would never suspend our license." If you were in compliance with DEA regulation and you were requesting an enhancement, how would that trigger a response in the nature of "we are 'such big players' that DEA would never suspend our license"?
MR. O'CONNOR: Objection to form.
A. I don't know what example that Karen is referring to in this -- in her comment.
BY MR. GOTTO:
Q. You don't recall any discussions with her on that point in this time frame?
A. No.

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Q. Did Ms. Harper ever express to you any frustration with the slow pace of enhancing the SOM program?
MR. O'CONNOR: Objection to form.
A. Not that I can recall.
BY MR. GOTTO:
Q. It took quite a while from when you began working on enhancing the program until there actually was an enhanced program in place, wasn't it?
MR. O'CONNOR: Objection to form.
A. I don't know what that time frame is. I don't know what a while is.
BY MR. GOTTO:
Q. More than three years?
A. I don't know, because they were working on it from the corporate aspect.
Q. In terms of when you were first aware of there being work on enhancing the SOM program until the time when the enhanced program was actually implemented, that was more than three years, wasn't it?
MR. O'CONNOR: Objection to form.
A. I don't remember. We were constantly

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working on it. There was always a program in place, we were just always tweaking it, making it better.
BY MR. GOTTO:
Q. Were you personally frustrated with the pace at which the enhancement of the SOM program was taking place?
A. No, not that I can recall.
Q. And you don't recall Ms. Harper expressing any frustration in that regard?
A. No, not to me.
(Whereupon, Mallinckrodt-Spaulding-10 was marked for identification.)
BY MR. GOTTO:
Q. We've marked as Exhibit 10 a multi-page e-mail thread beginning at Bates MNK-T1_0001792949. Please take a moment to look at those e-mails, and tell me if you recognize them.
(Witness reviewing document.)
Q. I just have questions for you on the first page.
(Witness reviewing document.)
A. Okay.

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Q. In your e-mail on June 24th, you indicate "Patti is sharing with her group as well."
Who is Patti?
A. Patti Woznick was the purchasing manager.
Q. Okay. And what was her group?
A. The purchasing department, and the ARCOS coordinator at the time was reporting to Patti.
Q. Okay. And Ms. Harper was forwarding you some press reports regarding oxycodone and OxyContin, correct?
A. Yes.
Q. And what would be the reason for Patti sharing that information with her group?
A. Because she had a member of compliance on her team.
Q. Fair to say that by mid 2008 you were aware of the potential for diversion and abuse of oxycodone, correct?
A. Yes. Yes.
Q. And fair to say it was a matter of concern for Ms. Harper at that time?

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MR. O'CONNOR: Objection to form.
A. I can't speculate on what Karen felt or knew.
BY MR. GOTTO:
Q. You don't recall her expressing to you at that time any concerns about the potential for diversion or abuse of oxycodone?
MR. O'CONNOR: Objection to form.
A. Not at this time.
BY MR. GOTTO:
Q. When can you recall her first expressing any such concerns to you?
MR. O'CONNOR: Objection to form.
A. I don't remember exact dates or timelines.
BY MR. GOTTO:
Q. You understood in 2008, didn't you, that as a DEA registrant Mallinckrodt had an obligation to design and implement a suspicious order monitoring program, correct?
A. Yes.
Q. And you understood that a purpose of that program was to function as an anti-diversion mechanism, correct?

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MR. O'CONNOR: Objection to form.
A. I understood it to be a regulation in the CFR.
BY MR. GOTTO:
Q. Did you understand one of the purposes for suspicious order monitoring to deter diversion?
A. Yes.
Q. And you understood in 2008 that as a DEA registrant Mallinckrodt also had the obligation to take steps to protect against diversion of the controlled substances that it manufactured?
MR. O'CONNOR: Objection to form.
A. We had to maintain effective controls to detect diversion within the manufacturing site.
BY MR. GOTTO:
Q. Did you have an understanding as to whether Mallinckrodt had any duties with respect to controlling against diversion with respect to its products after they left the manufacturing site?
A. No.

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Q. Did you not have an understanding, or did you understand that it did not have any such obligation?
A. So my understanding was that we had an obligation to maintain effective controls from us to the customer, to our direct customer. Back in 2008 we didn't know about downstream customers, or have the inclination that we needed to be looking at downstream customers.
Q. Okay. And when you say "downstream customers," you mean your customers' customers, correct?
A. Yes.
Q. And when did you first -- when can you recall first beginning to conduct any inquiry into Mallinckrodt's customers' customers?
MR. O'CONNOR: Objection to form.
A. That would have been when we started looking at chargebacks.
BY MR. GOTTO:
Q. And do you recall when that was?
A. I don't.
Q. Do you recall what triggered that?
A. I don't. I don't know if it was

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something that somebody else saw on the SOM team or it was broader.
Q. Was the subject of conducting inquiry into your customers' customers something that was covered in any of the DEA-sponsored educational programs that you attended?
A. I vaguely remember one of the DEA conferences talking about know your customer's customer, but I don't know when that was.
Q. Do you recall if at that time Mallinckrodt was taking steps to know its customer's customer?
A. No, because I don't remember what the correlation time was.
Q. How about the Buzzeo conferences, do you recall that topic, knowing your customer's customer, being covered at any of those conferences?
A. No.
Q. Do you recall that in 2008 there was an initiative at Mallinckrodt to enhance the SOM program?
A. Yes.
Q. And do you recall what triggered that?

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A. No.
Q. How did you learn about that initiative?
A. The initiative of --
Q. Enhancing the SOM program.
A. Through Karen Harper.
Q. And was one of the reasons for that initiative increased DEA scrutiny with respect to Mallinckrodt's distributors?
A. I don't know that firsthand.
Q. Was one of the reasons any of the letters from Mr. Rannazzisi that you mentioned earlier today?
A. It could be.
Q. But you don't recall?
A. I don't recall exactly, no.
Q. Do you recall in 2008 being aware that diversion of prescription opioids was being identified publicly as a significant health issue?
MR. O'CONNOR: Objection to form.
A. I'm aware of it. I don't remember when I became aware of it.
(Whereupon, Mallinckrodt-Spaulding-11

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was marked for identification.)
BY MR. GOTTO:
Q. We've marked as Exhibit 11 a two-page DEA letter beginning at Bates MNK-T1_0000270069. Take a look at that, and tell me if you recognize that as one of the letters from Mr. Rannazzisi that you testified about earlier today.
A. Yes.
Q. Do you recall seeing this letter in late 2007 or early 2008?
A. I recall seeing it. I would assume it was when this letter was sent. I don't remember exactly.
Q. And do you recall who provided it to you?
A. So based on the stamp, this came into our regulatory affairs department, and they probably shared it with me.
Q. Okay. Do you recall when you first saw this letter if this provided any information with respect to DEA regulation of which you were not aware until you read the letter?
MR. O'CONNOR: Objection to form.

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A. I remember that the letter called out that they didn't want excessive order reports anymore. They only wanted orders that were suspicious.
BY MR. GOTTO:
Q. Okay. And excessive order reports were something that you had provided previously, correct?
A. Yes.
Q. And did you stop doing that after receiving this letter?
A. I stopped doing it. I don't know that it was a result of receiving this letter or when.
Q. The second paragraph of the letter in the second line notes that manufacturers and distributors must maintain effective controls against diversion.
Do you see that?
A. Yes.
Q. You were aware of that before you received this letter, correct?
A. Yes.
Q. A little later in that paragraph,

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about halfway through there's a sentence that says "The regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system."
Do you see that in that system to disclose suspicious orders?
A. Yes.
Q. You were aware of that before you received the letter, correct?
A. Yes.
Q. In the following paragraph, the second sentence says "Filing a monthly report of completed transactions does not meet the regulatory requirement to report suspicious orders."
Were you aware of that before you received this letter?
MR. O'CONNOR: Objection to form.
A. I'm not following where you are in the letter.
BY MR. GOTTO:
Q. I'm sorry. The third paragraph, second sentence, "Filing a monthly report."
A. Okay.

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Q. Were you aware of what that sentence said before you received this letter?
MR. O'CONNOR: Same objection.
A. I don't remember.
BY MR. GOTTO:
Q. Two sentences later in that paragraph it says "Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels."
Do you see that?
A. Yes.
Q. Were you aware of that before receiving this letter?
A. I don't remember.
Q. But in any event, you were aware of it after you read this letter, correct?
A. Yes.
Q. Was it your understanding in late 2007, early 2008 that Mallinckrodt's procedures complied with that requirement, namely to conduct an independent analysis of suspicious orders before completing a sale to determine

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whether the controlled substances were likely to be diverted from legitimate channels?
MR. O'CONNOR: Objection.
A. Yes.
BY MR. GOTTO:
Q. What did that independent analysis consist of in this time frame?
A. I don't remember exactly. It was being done at corporate.
Q. It's not something you were involved in at this time?
A. I don't think so. I don't remember.
Q. Do you know who at corporate was involved in that?
A. Customer service managers.
Q. The next paragraph says "The regulation specifically states that suspicious orders include orders of an unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."
Do you see that?
A. Yes.
Q. Were you aware of that before you received this letter?

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A. Yes.
Q. On the second page, the first paragraph on that page says "Registrants that rely on rigid formulas to" determine "whether an order is suspicious may be failing to detect suspicious orders."
Do you see that?
A. Yes.
Q. Were you aware of that before receiving this letter?
A. I don't remember.
Q. The following sentence says "For example, a system that identifies orders as suspicious only if the total amount of the controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient."
Do you see that?
A. Yes.
Q. Were you aware before receiving this letter that a system of the type described in that sentence is insufficient?
A. I don't remember.
Q. Do you know if at this time

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Mallinckrodt's SOM program -- well, do you know if at the time of this letter the description that I just read from this letter would apply to Mallinckrodt's SOM program as it was followed in this time frame?
MR. O'CONNOR: Objection to form.
A. I don't know what the algorithm in place was at the time of this letter.
BY MR. GOTTO:
Q. Okay. You can set that aside.
(Whereupon, Mallinckrodt-Spaulding-12 was marked for identification.)
BY MR. GOTTO:
Q. We've marked as Exhibit 11 a one-page document MNK-T1_0000496062, Suspicious Order Monitoring Team Charter.
MR. O'CONNOR: Counsel, I think it's 12.
MR. GOTTO: I'm sorry. Is it 12?
MS. REYES: It is 12.
MR. GOTTO: Sorry. I apologize. Exhibit 12.
MR. O'CONNOR: No problem.
BY MR. GOTTO:

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Q. Updated 4/7/11. Take a look at that document, if you would, tell me if you recognize it.
(Witness reviewing document.)
A. Okay.
Q. Do you recognize that document?
A. No, I don't remember it.
Q. Appears to be a team charter for the SOM team. You're listed on -- as a member of the steering committee.
Do you see that?
A. Yes.
Q. And is that consistent with your recollection that you were a member of the SOM steering committee at least as of April 7 of 2011?
A. Yes.
Q. Do you recall when you became a member of the steering committee?
A. No.
Q. When you were a member, do you recall -- are you still a member of the steering committee?
A. Yes.

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Q. And does the steering committee meet regularly?
A. Yes.
Q. How frequently?
A. Monthly.
Q. Has that been the case at least since April of 2011?
A. Yes.
Q. Does it maintain minutes of meetings?
A. Not that I'm aware of.
Q. Any other formal documentation of its actions or deliberations?
A. No.
(Whereupon, Mallinckrodt-Spaulding-13 was marked for identification.)
BY MR. GOTTO:
Q. We've marked as Exhibit 13 a two-page document starting MNK-T1_0007026341. Please take a look at those pages, and tell me if you recognize them.
(Witness reviewing document.)
A. Yes.
Q. And what are they?
A. So this is actually -- I know the

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header says suspicious orders, but these are what we call as peculiar or unusual orders, so they're hits to the algorithm.
Q. Okay. Your cover e-mail, which is dated in April of 2014 to Ms. Harper, says "I can recall having a suspicious order monitoring system in place of some type with the start of distribution activities from Hobart 2001, however the attached is the earliest SOM report that I have in my e-mail system." And the attachment is from December of 2003, correct?
A. Yes.
Q. And this identifies four transactions. And I take it from your earlier answer these were identified as peculiar, correct?
A. Yes.
Q. And is it the case that none of these were ultimately determined to be suspicious?
A. Correct.
Q. And I think you've testified earlier the only order that you can recall being identified as suspicious was the fentanyl order to the vet clinic, correct?
A. The only one I know of, yes.

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Q. Okay. Do you recall why you sent this report to Ms. Harper in 2014?
A. She would have had to have requested it is the only reason I would have sent it.
Q. Now, in your cover e-mail you mention a suspicious order monitoring of some type from 2001. Was there a written suspicious order monitoring program in place before 2008?
MR. O'CONNOR: Object to form.
A. I don't know that it was written, that there was a written policy on it.
BY MR. GOTTO:
Q. Okay. So you don't recall seeing a written policy prior to 2008?
A. No.
Q. How did you come to know what the program was if it wasn't written?
A. Because Elizabeth McPhail at the time would have trained me on what to look for in the orders.
Q. And what do you recall her training you on in that regard?
A. To look at the orders that come out, and if they were of concern to research them

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further.
Q. And did she train you as to what characteristics of an order might raise concern?
A. No, because we really didn't have a whole lot of information of what was unusual.
Q. And so, for example, the orders identified as peculiar in the attachment to Exhibit 13, do you recall how you identified those orders as peculiar?
A. So the system would have ran these orders against whatever algorithm was in place at that time, and then these orders, these orders went on hold. So the report is saying their previous year-to-date average is 643, and this order was for 1,380.
Q. Okay. So these orders were identified by application of the algorithm that you understand was in place at the time?
A. Yes.
Q. But you don't know what the components of that algorithm were, correct?
A. All I know, it was based on previous history. I don't know the specifics.
Q. Okay. You can set that aside.

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(Whereupon, Mallinckrodt-Spaulding-14 was marked for identification.)
BY MR. GOTTO:
Q. We've marked as Exhibit 14 a single-page document, MNK-T1_0004282621. It's a 2007 e-mail from you to Sarah Heideman.
First of all, who was Sarah Heideman?
A. I don't remember.
Q. Okay.
A. I don't know.
Q. In the body of your e-mail -- first of all, no reason to doubt you sent this e-mail, correct?
A. No.
Q. The body of your e-mail, you say "DEA requires us to report any 'suspicious orders'. IS programmed a report that takes last year's average YTD and comes up with a formula and anything outside of that formula shows on this report."
Is that the algorithm that you're referring to?
A. Yes.
Q. And you have -- you ask Ms. Heideman

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to take a look and let you know what she thinks.
But you don't recall who Ms. Heideman was or why you sent her this e-mail?
A. Based on the context of this e-mail, it leads me to believe Sarah Heideman was the project -- or the account manager for Walmart, because I'm asking her specifically about Walmart orders.
Q. Okay. And you note in your e-mail, "It appears to me that Walmart is ordering double what was last years' YTD amount, more than the 20 percent market share increase."
Your reference there to market share, what are you referring to?
A. So we would have received information from the marketing group as to which customers have -- which have how much of the market share. So at this time I must have been advised by somebody in marketing that Walmart had 20 percent market share.
Q. Or 20 percent market share increase?
A. Yeah. Yes.
Q. Okay. So you're comparing that increase to the increase in the size of their

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order, is that what you're saying in this sentence?
A. YTD is year-to-date, so the formula at that time was taking the last year's year-to-date average, and this order was double their last year year-to-date average.
Q. And so would this -- is this e-mail an example of your looking at an order that had been identified as peculiar to determine whether it was suspicious?
A. At this time, yes.
Q. And you did that by providing this information to Ms. Heideman and asking her for some feedback on it?
A. Yes.
Q. And do you recall if you ultimately concluded whether this order was suspicious or not?
A. It wasn't reported to DEA, that I'm aware of.
Q. Okay.
(Whereupon, Mallinckrodt-Spaulding-15 was marked for identification.)
BY MR. GOTTO:

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Q. We've marked as Exhibit 15 a two-page document beginning at MNK-T1_0000274399, an e-mail exchange involving you and Ms. Harper, "Re: Controlled Substance Suspicious Order Monitoring Team Update." Take a look at those e-mails, and tell me if you recognize them.
(Witness reviewing document.)
A. Okay.
Q. Okay. Do you recognize those e-mails?
A. No, I don't remember them specifically.
Q. Okay. The second e-mail on the page from you to Ms. Harper dated June 17, do you see that?
A. Yes.
Q. Any reason to doubt you sent that e-mail?
A. No.
Q. Okay. You say to Ms. Harper, the first paragraph suggests on the customer checklist, "fill in what type of DEA registration so that we may be able to identify if a customer is ordering a suspicious amount against a specific registration type."

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What did you mean by that?
A. So if a customer that's listed as a researcher is ordering a huge amount of product, that would not be normal for a researcher license.
Q. Okay. And the customer checklist that you're referring to here, what was that?
A. To the best that I recall, there was -- the SOM corporate team was developing checklists to be sent out to our customers.
Q. Was this part of the enhancement of the SOM?
A. Yes.
Q. The last paragraph of your June 17th, or the last substantive paragraph says "With the new procedures, what kind of report will I send to the DEA? I realize that we will DEA report any order that is deemed suspicious by yours and Bill's group, but what if we go a quarter without a suspicious order?"
Do you see that?
A. Yes.
Q. So was your -- does that indicate that up until this time there was a regular quarterly

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report you were sending to the DEA?
A. It was the excessive orders report.
Q. Okay. And so does that paragraph indicate that you were not going to be providing that report to the DEA anymore? Correct?
A. Correct.
Q. And so what was the answer to the question that you posed in that paragraph?
A. I don't remember.
Q. You can set that aside.
Do you know who Bill Rausch was?
A. Bill Rausch --
Q. Rausch.
A. -- or Jim Rausch?
Q. Jim Rausch, I'm sorry.
A. Jim Rausch, yes.
Q. Who was he?
A. He was a customer service manager.
Q. Did he have any involvement at any time that you can recall in the SOM process?
A. Yes, he was the customer service manager reviewing the peculiar order report.
Q. Okay. And did he provide reports to the DEA from time to time that you know of?

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A. I don't know what he provided.
(Whereupon, Mallinckrodt-Spaulding-16 was marked for identification.)
BY MR. GOTTO:
Q. We've marked as Exhibit 16 a two-page document beginning at Bates MNK-T1_0002940798. Please take a look at those and tell me if you can identify them.
(Witness reviewing documents.)
A. Okay.
Q. Do you recognize those documents?
A. Yes.
Q. What are they?
A. These were the quarterly reports that I was combining and sending to DEA.
Q. Okay. And these were -- what is reported on the report?
A. I'm not sure I understand your question.
Q. I'm sorry. How does some -- how does an order -- what is it about an order that causes you to include it on this report?
A. So if it hits the criteria for the algorithm.

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Q. Okay. So these would be, again, peculiar orders under the Mallinckrodt terminology?
A. Yes.
Q. Okay. And so did you report all peculiar orders on a quarterly basis to the DEA for some period of time?
A. We reported all orders that -- these are all clinic orders.
Q. Clinic orders that had been identified as peculiar?
A. Yes.
Q. As compared to what other types of orders?
A. So the distributors have been removed.
Q. Okay. And what was the reason for that?
A. I don't remember specifically. I remember being told not to include the distributors into the report, but I don't remember who told me not to include the distributors.
Q. Would it have been someone other than Ms. Harper?

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A. It could have been.
Q. Okay. And you don't remember -- you weren't given a reason for that, I take it?
A. I know that I was told not to include them, but I can't remember by whom. It could have been any number of people.
Q. So in Exhibit 15, that was an e-mail in 2008 in which you posed the question about what kind of report will you be sending to the DEA going forward.
Do you see that?
A. Yes.
Q. In 2010, judging from Exhibit 16, in 2010 you were still providing some sort of quarterly report to the DEA, correct?
A. Yes. Well, this was -- the last report was 2008. My e-mail to Karen was 2010, but the last report was 2008.
Q. Okay. So your 2010 e-mail is attaching a 2008 report?
A. Yes.
Q. Okay. So the attachment to Exhibit 16 is the final report that you sent to the DEA, the final quarterly report?

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A. Yes.
Q. Okay. And so after the report that's attached to Exhibit 16, what, if any, report did you provide to the DEA with respect to orders that were identified as peculiar but were not identified as suspicious?
A. So what reports did we make to the DEA that were peculiar but not suspicious?
Q. Yes.
A. In what time frame?
Q. Well, after the report that is attached to Exhibit 16.
A. Right. We stopped this because this was basically the excessive order report, and the letter came out that said they didn't want the excessive order report, so that's why we discontinued sending them to DEA. And then we would have only reported suspicious orders.
Q. Okay.
A. In 2012, one of the iterations in the enhancements involved sending the peculiar order report, at this time we called it unusual order report, to DEA twice daily.
Q. And that was in 2012?

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A. Roughly, yes.
Q. Okay. And do you continue -- is that procedure still in place?
A. Yes.
Q. Okay. So from the attachment to Exhibit 16, after that report and prior to the time when you in 2012 began the twice daily unusual order report to the DEA, was there any other reporting to the DEA other than if a report was -- if an order was determined to be suspicious?
A. Not by me, but I don't know if DEA -- or if corporate was sending anything to DEA.
Q. Okay. But as far as reports that you're aware of, you're not aware of any during that time period?
A. Correct. 2008 was the last of the quarterly excessive order reports. In 2012 started the peculiar order reports.
Q. Okay. You can set that aside.
(Whereupon, Mallinckrodt-Spaulding-17 was marked for identification.)
BY MR. GOTTO:
Q. We've marked as Exhibit 17 a

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multi-page e-mail thread, MNK-T1_0005663239 is the beginning. Take a moment to look at those.
My questions are principally about your March 5, 2012 e-mail that begins the thread.
(Witness reviewing document.)
A. Okay.
Q. Do you recognize those e-mails?
A. I'm sorry?
Q. Do you recognize those e-mails?
A. No.
Q. Okay. Turning to your March 5, 2012 e-mail, which is on the third page, any reason to doubt you sent that e-mail?
A. No.
Q. Okay. So this is an e-mail that you send to a number of persons regarding an order from Quest Pharmaceuticals, correct?
A. Yes.
Q. And you indicate "I am unsure of the Product Manager for Hydrocodone and the NAM for Quest," correct?
A. Yes.
Q. And that's the reason you sent it to

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all those parties, right?
A. Correct.
Q. Okay. Was there a -- well, strike that.
So the order from Quest had been identified as a peculiar order, is that fair?
A. Unusual, yes.
Q. Peculiar or unusual?
A. Yeah.
Q. Meaning that it triggered the -- whatever the algorithm was in place at the time, this triggered it?
A. Yes.
Q. Okay. And you indicate that the "items are double and in some cases triple the quantity previously ordered." Would your procedure at this time in 2012 have been to inquire of the product manager or the NAM to get further information with respect to an order that triggered the algorithm?
A. Yes.
Q. Okay. And here you weren't sure who those individuals were, correct?
A. Correct.

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Q. Did you have any program in place to be made aware of who the project manager -- product manager and NAMs were for particular products or customers?
A. No.
MR. O'CONNOR: Objection to form.
A. Because they could change. So NAM is national account manager, and the product manager.
BY MR. GOTTO:
Q. Okay. And so when you had a peculiar or unusual order, was it your practice to inquire of both the product manager and the national account manager?
A. Depends on the circumstances and the product.
Q. Okay. Did you ever have any difficulty in receiving responses either from product managers or national account managers with respect to inquiries that you made regarding peculiar orders?
A. Sometimes we'd have to send them a reminder e-mail if they were travelling that the order was still on hold and we were awaiting

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information.
Q. Did you ever make inquiry of the customer service department to gain further information with respect to orders that had been identified as peculiar?
A. Yes.
Q. And who did you make inquiry of in the customer service department?
A. It depends on the customer service rep assigned to the account.
Q. Okay. So in this example on March 5th of 2012, are you making inquiry here of customer service?
A. No.
Q. And why not?
A. Because customer service may not know why their order is higher. The product manager or the account manager may. I would inquire to customer service if I suspected that an order had been duplicated. There might have been an order entry error. But in this case, because of the order quantities, I went to the account manager who would know what the customer was ordering.

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Q. Okay. Do you know who Cathy Stewart was?
A. Yes.
Q. Who was she?
A. She was a customer service manager.
Q. Did you interact with her from time to time?
A. Yes.
Q. And she had customer service reps who reported to her, correct?
A. Yes.
Q. And your March 5, 2012 e-mail, one of the persons that you address it to is Victor Borelli, correct?
A. Yes.
Q. And did you deal with Mr. Borelli from time to time?
A. Yes.
Q. Did Ms. Stewart ever express to you, that you can recall, that one or more of the customer service reps who reported to her had expressed the view that Mr. Borelli would tell them anything to get a sale?
MR. O'CONNOR: Objection to form.

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A. Not that I remember.
BY MR. GOTTO:
Q. Okay. You can set that aside.
(Whereupon, Mallinckrodt-Spaulding-18 was marked for identification.)
BY MR. GOTTO:
Q. We've marked as Exhibit 18 a two-page e-mail thread beginning at Bates MNK-T1_0000280632. Take a moment to look at those e-mails, if you would.
(Witness reviewing document.)
A. Okay.
Q. And do you recall this e-mail exchange?
A. Yes.
Q. Okay. What do you recall of that?
A. Karen was alerting me to some -- she had compiled a timeline and had sent me the timeline, and then was letting me know that all the orders had been reviewed by the customer service manager, and then later on in the e-mail she corrects terminology listed below.
Q. Okay. In Ms. Harper's e-mail, she -- the first e-mail, October 31, "In an effort to

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provide you with as much information as possible, I have attached a (lengthy) chronology of events relating to Mallinckrodt Suspicious Order Monitoring."
Do you see that?
A. Yes.
Q. Let me hand you what we've marked as Exhibit 19, and you can tell me if that's the attachment.
(Whereupon, Mallinckrodt-Spaulding-19 was marked for identification.)
BY MR. GOTTO:
Q. Exhibit 19 is a multi-page document beginning at page MNK-T1_0000477900. Can you tell me if that's the chronology that Ms. Harper is referring to?
A. Yes.
Q. Okay. And you're familiar with that chronology, right?
A. At a high level, yes.
Q. Okay. Did you have occasion ever to provide this chronology to DEA?
A. We met in -- we went and met with DEA. We didn't provide a document, I don't recall.

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Q. Okay. And in Ms. Harper's October 31 e-mail, she says "during the last two years, all Peculiar Orders...were deemed to be okay and none rose to the level of Peculiar."
Do you know if she meant there that none rose to the level of suspicious?
MR. O'CONNOR: Objection.
A. She did. In the earlier e-mail above she clarifies that --
BY MR. GOTTO:
Q. Okay.
A. -- she meant none rose to the level of suspicious.
Q. Okay. And that's consistent with your recollection you've already testified to in terms of orders being identified as suspicious, correct?
A. Yes.
Q. She gross on to say "It is significant to note that neither Sunrise or Harvard triggered the algorithms that were in place for direct customers because we were looking at overall purchase trends for each distributor, not reviewing where the distributors were

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sending our product (and our program met CFR requirements)."
And is that the phenomenon you testified about earlier today, looking at ship to rather than bill to?
MR. O'CONNOR: Objection to form.
A. No, that's different.
BY MR. GOTTO:
Q. Okay. In what way is this different?
A. So Karen is referring to downstream customers, so those wouldn't have triggered because we were only looking at our direct shipments to Sunrise and to Harvard. We weren't looking at where Harvard was shipping, or Sunrise.
Q. Okay. And she indicates in the last sentence of that paragraph that the program has now been expanded in October of 2010 to look at customers' customers, correct?
A. Based on this e-mail, yes.
Q. Okay. And was that your recollection as well, that in late 2010 the SOM program was expanded to include a review of Mallinckrodt's customers' customers?

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MR. O'CONNOR: Objection to form.
A. Only based on this e-mail.
BY MR. GOTTO:
Q. You don't otherwise recall that?
A. No.
Q. Can you recall at any time in connection with suspicious order monitoring you personally reviewing information regarding Mallinckrodt's customers' customers?
A. I was involved in reviewing chargebacks, but I don't remember when that started.
Q. And that would have given you information about Mallinckrodt's customers' customers, right?
A. If they applied and participated in chargebacks, yes.
Q. Okay.
(Whereupon, Mallinckrodt-Spaulding-20 was marked for identification.)
BY MR. GOTTO:
Q. We've marked as Exhibit 20 a two-page document beginning at Bates MNK-T1_0002357150, appear to be notes from the 11/1/10 meeting at

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the DEA Albany office.
Do you recognize those notes?
A. Yes.
Q. And it indicates that you and Mr. Nikolaus attended the meeting, correct?
A. Yes.
Q. And you recall the meeting, correct?
A. Yes.
Q. Can you recall other similar meetings with the DEA Albany office?
MR. O'CONNOR: Objection to form.
A. Similar, meeting with them about this topic or about any topic?
BY MR. GOTTO:
Q. Well, back that up.
Did you have regular meetings at the DEA's Albany office?
A. No.
Q. Okay. So was this meeting requested by the DEA?
A. No, this meeting was requested by Mallinckrodt.
Q. And for what purpose?
A. To explain to them our SOM program.

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Q. And what was the reason that you wanted to explain the SOM program to the DEA at this point?
A. I don't remember specifically.
Q. Under "General Feedback from DEA Albany," it states "The direct and indirect customer data was presented to DEA. DEA was alarmed by the data but not surprised."
Do you see that?
A. Yes.
Q. And were these your notes or Mr. Nikolaus's notes?
A. They were my notes.
Q. Okay. So when you say they were alarmed by the data but not surprised, what do you mean? How did they express that?
A. I remember them looking at the data and going "wow." And then a comment by someone that was in attendance, I don't remember specifically who, saying they're not surprised by that.
Q. What was your reason for providing the direct and indirect customer data to the DEA at this time?

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A. Because we were incorporating chargebacks into our SOM program, so when explaining the SOM program we showed them what we were looking at direct data, and what we were looking at indirect data.
Q. And was this the first time that you began to look at the direct and indirect customer data?
MR. O'CONNOR: Objection to form.
BY MR. GOTTO:
Q. In this time frame?
A. I don't remember when I started. We were doing it at this time.
Q. If you look at Exhibit 18, I believe Ms. Harper indicated in her e-mail dated October 31 that "the program was expanded within the last month to our customers' customers." So would that indicate that this is -- that the meeting occurred on November 1st, right, so would that indicate that at this time this was when you first began looking at the indirect customer data?
MR. O'CONNOR: Objection to form.
A. Based on this e-mail. But I don't

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remember.
BY MR. GOTTO:
Q. Okay. You can set that aside.
(Whereupon, Mallinckrodt-Spaulding-21 was marked for identification.)
BY MR. GOTTO:
Q. Exhibit 21 is a single-page e-mail thread MNK-T1_0000270021. Take a look at that e-mail, appears to be an e-mail from you to Heather White, and tell me if you recognize it.
(Witness reviewing document.)
A. Okay.
Q. Do you recognize that e-mail?
A. Yes.
Q. And Heather White was at the DEA, correct?
A. Yes.
Q. And what was your reason for providing the information in your November 30th e-mail to Ms. White?
A. Because when we spoke to her at the on-site meeting we advised that we were sending out distributor letters based on the data that we had reviewed.

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Q. And you talk about three distributors, Masters, KeySource, Cedardale. I think you indicated earlier in your testimony today that those are three distributors that were audited in approximately this time frame, correct?
A. Yes.
Q. And ultimately all of those distributors had their DEA licenses terminated, didn't they?
MR. O'CONNOR: Object to the form.
A. I don't know that they were terminated.
BY MR. GOTTO:
Q. At least suspended?
A. I know of Masters and KeySource. I don't remember Cedardale.
Q. Do you recall -- you testified a little earlier today regarding the Cedardale audit. Do you recall if at the time of the Cedardale audit you had any information regarding whether Cedardale had suspended sales to any of its existing customers?
A. I don't remember having any of that information at that time.

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Q. Would that information have been pertinent to your audit at that time?
A. If Cedardale had been suspended shipping to pharmacies?
Q. If Cedardale itself had determined that it would suspend certain of its customers.
A. We would have documented that in our audit notes.
Q. That would have been of interest to you?
A. It would have been documented.
Q. But you don't recall being aware of that as you sit here today?
A. No.
Q. Do you recall if you made an inquiry in that regard as part of the audit?
A. I'd have to look at my notes.
Q. Okay.
(Whereupon, Mallinckrodt-Spaulding-22 was marked for identification.)
BY MR. GOTTO:
Q. Exhibit 22 is a two-page e-mail thread beginning at Bates MNK-T1_0001519526. Take a moment and tell me if you recognize those

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e-mails.
(Witness reviewing document.)
A. Okay.
Q. Do you recognize those e-mails?
A. I don't remember them, no.
Q. Okay. The main e-mail, the August 6, 2012 e-mail from you to Heather White, "is a list of distributors that we have met with in person or by telephone to discuss SOM issues within the last twelve months."
Do you recall having those personal or telephonic meetings with the listed distributors?
A. I remember having telecons, yes.
Q. And what would cause you to have a personal or telephonic meeting with a distributor regarding SOM issues?
A. So the SOM team would decide whether we needed to do an on-site audit or if we could do a telecon in which we'd review with them their orders and the data, their chargeback data.
Q. And what is it that would cause the team to decide that such an audit or

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teleconference was required?
A. I don't remember any specifics why we would.
Q. Of the parties listed in this e-mail, do you recall how any of these were personal meetings as compared to teleconferences?
A. In 2012, no, because some of the on-site audits were conducted by people in corporate, so I don't remember specific. I remember doing -- I was only involved in the Cedardale audit on-site, and I remember being involved in telecons, but which ones specifically, I'd have to look at notes.
MR. GOTTO: Okay. Why don't we take a break.
THE VIDEOGRAPHER: The time is 2:28 p.m., and we're off the record.
(Whereupon, a recess was taken.)
THE VIDEOGRAPHER: The time is 2:42 p.m., and we're on the record.
(Whereupon, Mallinckrodt-Spaulding-23 was marked for identification.)
BY MR. GOTTO:
Q. Ms. Spaulding, we've marked as

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Exhibit 23 a multi-page document beginning at Bates MNK-T1_0000289371. It's an e-mail along with an attachment. Please take a look at that and tell me if you recognize it.
I guess it actually has a series of attachments, I should say.
(Witness reviewing document.)
A. Okay.
Q. Do you recognize those documents?
A. No, I don't remember them, only based on the e-mail.
Q. Okay. So your e-mail, your October 18th e-mail to Ms. Harper, any reason to doubt you sent that?
A. No.
Q. And you make reference in your e-mail to "tried several different ways to make a report that we could use across sites to be consistent in our practices."
Do you see that?
A. Yes.
Q. So can you describe for me what you were trying to accomplish in this regard?
A. So we were looking to make a

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centralized place between all three sites to document any correspondence that we had with DEA, so I feel the need to clarify that even though we called them SOM contacts or inquiry, they were not always indicative of a suspicious order. It was part of the overall umbrella program of suspicious order monitoring.
Q. Okay. And so what would be an example of something that's under that overall umbrella but was not indicative of the suspicious order?
A. So, for example, in this report 11-01, this was the ARCOS unit contacting me about two NDC errors -- or I'm sorry, contacting Mary Lewis and Webster Groves. One that was specific to me was line 5, so report 11-03 was to contact DI Heather White because we had a complaint about Methadose 40-milligram bottle complaints.
Q. Okay. And then one of the attachments is -- it's called a DEA Suspicious Order Monitoring Report?
A. Yes.
Q. And what is that document?
A. So this was a template that we were using to how we would document a formal

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suspicious order.
Q. Okay. And so this is not a DEA form, right? This is something you -- or Mallinckrodt created?
A. Correct. This one is -- it says up at the top is an example only.
Q. Okay. You can set that aside.
(Whereupon, Mallinckrodt-Spaulding-24 was marked for identification.)
BY MR. GOTTO:
Q. Exhibit 24 is a multi-page document beginning at MNK-T1_0000282467, appears to be an e-mail you prepared attaching the notes of an HDMA conference that you attended.
Could you take a look at that and confirm for me, if you can, that that's what the exhibit consists of?
(Witness reviewing document.)
A. Yes.
Q. Okay. Do you recall this conference?
A. Vaguely. Not in detail, but yes.
Q. Did you make a practice of keeping notes like these at each conference you went to and then memorializing them?

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A. Not every conference, only if I was asked to produce a conference or a trip report.
Q. Okay. And who would have asked you to do that?
A. My manager at the time.
Q. If you turn to the next-to-last page of the document, the one that ends in Bates 473 -- I guess actually starting at the bottom of the third-to-last page that begins at Bates 472, there's a reference to a presentation by a David Durkin regarding controlled substance monitoring, 2011 update.
Do you see that?
A. Yes.
Q. And the main bullet items, the third one on the following page is "Reviewed the 12/2007 DEA Letter to registrants."
Do you see that?
A. Give me one moment, please.
Q. Sure.
(Witness reviewing document.)
A. I'm sorry, which bullet were you --
Q. There's -- the second main bullet on the page that ends in 473 says "Reviewed the

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12/2007 DEA Letter to registrants."
Do you see that?
A. Yes.
Q. And that's the letter from Mr. Rannazzisi that we looked at a little earlier today, correct?
A. I'm not looking at the date, but I believe so, yes.
Q. Okay. You can set that aside.
(Whereupon, Mallinckrodt-Spaulding-25 was marked for identification.)
BY MR. GOTTO:
Q. Exhibit 25 is a multi-page document bearing Bates MNK-T1_0000283244, appears to be an e-mail you prepared transmitting notes you took at a Buzzeo webinar in April of 2011. If you could take a look at that and confirm for me that that's what those materials are.
A. Yes.
Q. Okay. Do you recall this particular webinar?
A. Not this one, no.
Q. The notes that you took here, did you have occasion to go over these with Ms. Harper

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or anyone else at Mallinckrodt?
A. Go over them? I sent them to her, but I didn't -- I don't know that I reviewed or discussed them with her.
Q. Okay. On the second page of your notes up at the top where it says "SOM System Recommendations - Total SOM Solution," do you see that?
A. Yes.
Q. The second item is "Determine legitimacy before shipping for each and every order."
Do you see that?
A. Yes.
Q. Did you understand at this time that an SOM program -- that part of an effective SOM program should be that before an order that was identified -- that was questioned in any way shipped, a determination needed to be made as to whether or not it was suspicious?
MR. O'CONNOR: Objection to form.
A. At this time back in 2011 did I know that?
BY MR. GOTTO:

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Q. Yes.
A. I don't know if I knew it at the time. I mean, I understood what it says when they spoke of it.
Q. Okay. Do you have an understanding as to whether in this time frame in 2011 Mallinckrodt had procedures in place to assure that orders that had been identified as peculiar or unusual would not be shipped until it was determined whether or not there would be -- they were suspicious?
MR. O'CONNOR: Objection to form.
A. So based on our review of documents prior in 2010, we discussed that we were reviewing orders before shipping.
BY MR. GOTTO:
Q. Do you know if there were ever occasions when an order that was identified as peculiar or unusual was shipped before the determination was made as to whether it was suspicious?
A. Not by me, but I wasn't doing -- I'm not aware. I wasn't doing the review.
Q. Do you recall in 2010 there being a

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change to the algorithm whereby the comparison of an order to the prior year's ordering pattern was changed from whether it was more than [redacted] times the average to whether it was more than [redacted] times the average?
A. I remember that there was a change. I don't remember whether it was specifically in 2010 or not.
Q. Okay. But you do remember that [redacted] to [redacted] change being made at some point?
A. Yes.
Q. Do you remember what the reason was for that change?
A. No.
Q. Were you involved in the decision to make that change?
A. I would have been on the SOM team that discussed the change, but it would have been approved by the management.
Q. Do you remember who suggested the change?
A. No.
Q. And you don't remember any of the reasons that were offered in support of it?

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A. No, not specifically.
(Whereupon, Mallinckrodt-Spaulding-26 was marked for identification.)
BY MR. GOTTO:
Q. Exhibit 26 is a two-page document beginning at Bates MNK-T1_0000288483, appears to be a letter from you to Heather White at the DEA. And take a look and tell me if you can confirm that that's a letter that you sent on or about November 1 of 2010.
(Witness reviewing document.)
A. Yes, this is a letter I sent.
Q. Okay. And this is notifying Ms. White of the inclusion in the SOM program of review of chargeback data, correct?
A. Yes.
Q. And do you recall, after the chargeback data review was included as part of the SOM program, were there orders that were identified as peculiar or unusual solely as a result of the chargeback review?
A. So I don't think I understand. Chargeback are not orders. Chargeback are downstream.

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Q. Right. But you were, as of November, 2010, you were reviewing chargeback data as part of the SOM process, correct?
A. Yes.
Q. And so my question is, once you started reviewing the chargeback data, did that result in the identification of any orders as peculiar or unusual or suspicious under the SOM program?
A. No, because there's no way to directly tie a chargeback order credit to a direct order.
Q. And so how was the chargeback data used as part of the SOM program from and after November of 2010?
A. To review if a downstream customer, so a customer's customer, may pose a risk to bring that attention to the down-direct customer.
Q. And how would you identify as part of the chargeback review the potential for that downstream customer to pose a risk?
A. So based on the red flags and the enforcement action in comments from DEA at training sessions through the DEA seminars, we developed a red flags list, and we would look at

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chargebacks to see if a pharmacy had a large quantity, we would then ask the distributor for due diligence and ask them to check for any of these red flags as part of the review.
Q. So is it fair to say Mallinckrodt itself would not take any action directly with respect to this indirect customer, but would instead provide information to Mallinckrodt's direct customer?
MR. O'CONNOR: Objection to form.
A. We would do both. So we would work with the distributor to bring to their attention that we're potentially seeing chargebacks, because a distributor would only see what they sold, they wouldn't see if there was other distributors selling to them. And if the SOM team determined that the pharmacy was a significant risk, they would issue a restriction in which that pharmacy could no longer apply for chargebacks.
BY MR. GOTTO:
Q. Okay. So the pharmacy would -- it could continue to buy from a Mallinckrodt distributor, but it could not apply for a

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chargeback?
A. Correct.
Q. So the chargebacks, were they applied for by the pharmacies or by the distributor?
A. The chargeback is applied by the distributor to Mallinckrodt on behalf of the pharmacy.
Q. So it would have been possible for Mallinckrodt to inform the distributor that sales should not be made to that pharmacy, as compared to stating that Mallinckrodt would not pay chargebacks to that -- related to that pharmacy, correct?
MR. O'CONNOR: Objection to form.
A. No, we can't dictate who a distributor sells to and who they don't sell to.
BY MR. GOTTO:
Q. So if you knew that a distributor, for example, was selling to a non-registrant, you could tell the distributor, you need to stop doing that or we can't sell to you anymore, correct?
A. If we knew that they were selling to a non-DEA registrant, I believe we would alert DEA

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to that.
Q. And so if you knew that a distributor was selling to a pharmacy as to which there was sufficient red flags to where Mallinckrodt decided that it would no longer pay chargebacks with respect to that pharmacy, Mallinckrodt could have notified the distributor that if the distributor continued to sell to that pharmacy Mallinckrodt wouldn't sell to the distributor anymore?
MR. O'CONNOR: Objection to form.
BY MR. GOTTO:
Q. Right?
A. No, because then we could potentially jeopardize legitimate people from not getting their medicines. We prohibited the chargebacks as a financial disincentive to not sell Mallinckrodt to a pharmacy that we considered a risk. But we can't control the distributors and who they sell to. We have no influence whatsoever on who the customer base of any one distributor is. And if we had -- say you can't sell to that pharmacy anymore, that pharmacy could potentially go to another distributor and

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get Mallinckrodt product.
Q. And that's true, though, if you say we're not going to honor chargebacks, that pharmacy can continue to buy Mallinckrodt products even through that distributor, just not going to -- the chargeback won't be honored, correct?
A. Correct. It's a financial disincentive not to sell Mallinckrodt product, but we can't say who they can or can't sell to.
Q. Was the result of any chargeback data review ever provided to the DEA?
A. Can you say at that again, please?
Q. Yes.
So you engaged in -- from November, 2010 forward you were reviewing chargeback data as part of an evaluation as to whether there were red flags with respect to some indirect -- with respect to indirect customers, correct?
A. Yes. If we restricted a pharmacy from chargebacks, we notified DEA.
Q. Okay. And was there any follow-up from DEA that you can recall when there was any such notification given?

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A. Not that I can think of.
Q. What was the nature of the notification? What did you tell DEA?
A. We have a letter that we would notify sent to DEA saying these pharmacies have been restricted from Mallinckrodt chargebacks because they exhibit indicators of diversion.
Q. You can set that aside.
(Whereupon, Mallinckrodt-Spaulding-27 was marked for identification.)
BY MR. GOTTO:
Q. Exhibit 27 is a multi-page document beginning at Bates MNK-T1_0000422189. It's an e-mail thread from late 2010 into January of 2011. Take a moment and tell me if you recognize those e-mails.
(Witness reviewing document.)
A. Okay.
Q. Do you recognize these e-mails?
A. No.
Q. Okay. So the earliest e-mails in the thread are an exchange between Ms. Harper and Carol Svejkosky --
A. Yeah, Svejkosky.

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Q. Thank you. S-V-E-J-K-O-S-K-Y, just like it sounds.
-- in which Ms. Harper is requesting certain state concentration and customer sourcing data, correct?
A. Yes.
Q. And is that data that ultimately you came to be supplied with regularly?
A. Yes.
Q. Okay. And did that become part of the SOM program, reviewing that data on a monthly basis?
A. Yes.
Q. What was the state concentration report that Ms. Harper requests?
A. It looks at oxycodone 50-milligram and oxycodone 30-milligram by state instead of by pharmacy.
Q. And do you know what the reason was for conducting that review?
A. Based on at this time the enforcement action and the knowledge around Florida and other states being of concern.
Q. Okay. All right. You can set that

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aside.
(Whereupon, Mallinckrodt-Spaulding-28 was marked for identification.)
BY MR. GOTTO:
Q. Exhibit 28 is a two-page e-mail thread beginning at Bates MNK-T1_0000485790, e-mails from November of 2010. Take a moment and tell me if you recall these e-mails.
(Witness reviewing document.)
A. Okay.
Q. Do you recognize these e-mails?
A. I don't remember them.
Q. Okay. If you look at Ms. White's e-mail at the bottom of the first page to you on November 18th, she says "I know the standard answer regarding lot numbers. Can you please tell me which distributors this was sent to and if you had any chargebacks for the product in the Fort Lauderdale area? We can get an Administrative Subpoena if you need one."
Do you see that?
A. Yes.
Q. So do you know what she meant by "the standard answer regarding lot numbers"?

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A. No, I couldn't guess what she was referring to.
Q. Okay. So if you look at the first e-mail in the thread from Thanh Churchin, "Susan, can you check on this lot number for me," giving a case number. "The lot number came from a trash pull that IRS did."
Do you know what "lot number" means in this context?
A. Yes. It's the lot number that Mallinckrodt produced for that particular batch.
Q. Okay. And what would be the reason for using that lot number?
MR. O'CONNOR: Objection to form.
BY MR. GOTTO:
Q. What information would that give you?
A. We could trace the lot number to see who we sold it to, but then they would have to go to who we sold it to to trace who they sold it to.
Q. Okay. And so turning back to Ms. White's e-mail where she says "I know the standard answer regarding lot numbers," was the standard answer that you would give that

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information if there was -- in response to a subpoena?
A. I don't know what she meant.
Q. Do you recall ever informing Ms. White or anyone else at the DEA that certain information they sought would be provided only in response to a subpoena?
A. We usually request a subpoena if they want anything in writing, so it's pretty standard.
Q. Okay. And so there would be times when you would give them verbal information, but if they wanted that information in writing you'd tell them they needed to issue a subpoena?
A. Not during a -- not a shipping history report.
Q. You would not require a subpoena for that?
A. No. I'm sorry. We would require -- I would not give them that information verbally.
Q. Okay. And what's the reason for that?
A. Just any information that's provided to DEA always goes through our legal department.
Q. Well, there was certain information

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you would give DEA verbally, that if they asked for it in writing you'd require a subpoena, correct?
A. The information that we would give to them verbally would be routine information that they would ask regarding a process or a high level question. Anything that was documented or in detail like a shipping report would require a subpoena.
Q. Okay. So your November 18th e-mail to Karen Harper says "I can run a report on where we ship this lot number to. Does the chargeback system refer to lot numbers? If so" you can get a report, please. I'm sorry, "If so, can you get a report please."
So I take it at this time in November of 2010 you didn't know if the chargeback system contained the lot numbers for orders, correct?
A. Correct. Because what we looked at were reports that were generated from the chargeback system.
Q. Okay. And so the -- what information were you able to determine from reviewing a lot number?

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A. Where we shipped it to.
(Whereupon, Mallinckrodt-Spaulding-29 was marked for identification.)
BY MR. GOTTO:
Q. Exhibit 29 is a multi-page document beginning at Bates MNK-T1_0000561060, appears to be an e-mail exchange between you and Mr. Ratliff concerning a lot trace report. Take a look at those e-mails, tell me if you recognize them.
(Witness reviewing document.)
A. Okay.
Q. Okay. And so the first e-mail in the thread is from Mr. Ratliff, down at the bottom of the first page onto the second page, from Mr. Ratliff to you and Mr. Nikolaus, where he says "Oxy, lot," and gives a number, "is being transported from Florida to Eastern Tennessee in fairly significant quantities. They have original bottles and are currently looking for the source of loss in Florida. I will be receiving additional information soon."
Do you see that?
A. Yes.

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Q. Do you recall that e-mail?
A. Vaguely, yes.
Q. Okay. And then you respond to him on July 6th "Would you like me to run a lot trace report ASAP?"
A. Correct.
Q. And he responds "Yes." You run the report. Is the attachment to the e-mail the report?
A. Yes.
Q. And you say in your e-mail total quantity of bottles. You say "Lot beam for release."
What does that mean?
A. It means when it is released from our quality control labs and able to be shipped to market.
Q. Okay. And then "Shipped from DC."
What is DC?
A. Distribution center.
Q. Okay. On the dates, "and entire lot is depleted. 8 customers in total, 1 in Florida."
And then the eight customers are

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listed on the attachment, correct?
A. Yes.
Q. And so the attachment, is this typical of the information that a lot trace report would give you?
A. It's the exact information.
Q. Okay. You can set that aside.
(Whereupon, Mallinckrodt-Spaulding-30 was marked for identification.)
BY MR. GOTTO:
Q. Exhibit 30 is a two-page document beginning at Bates MNK-T1_0000371673, and appears to be an e-mail exchange between you and Ms. Harper in June of 2010 concerning a DEA and local law enforcement inquiry. Tell me if you recognize those e-mails.
(Witness reviewing document.)
A. Okay.
Q. Do you recognize those e-mails?
A. Yes.
Q. Okay. So in your June 17th e-mail to Ms. Harper, in the first paragraph you say that in recent months you "received several inquiries from both local law enforcement and DEA...in the

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State of Florida and surrounding states regarding lot trace shipping histories."

You go on a little later in the paragraph to say "In many of these inquiries, I noticed that Sunrise Wholesalers was one of our customers who had received the lot in question by the investigating officer. I did not always divulge that information unless requested specifically by the individual and never provided any information in writing as they were advised that they would need to send a subpoena to our legal department if they needed documentation of any kind."

Do you see that?

A. Yes.

Q. So what was your reason for not divulging that information to law enforcement unless specifically requested?

A. I don't remember the specifics of this situation back in 2010, but it's usually policy we don't discuss that information over the phone.

Q. But if you had -- if the law enforcement agent had specifically requested it,

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you would have divulged it over the phone, is that right?

A. I may have pointed them in the right direction to help with their investigation.

Q. And is there any reason that you would require them to specifically request the information before you would help them with the investigation?

MR. O'CONNOR: Object to form.

A. Because we didn't want to assume what they were looking for, and they didn't always give us details, so we didn't assume what they were looking for. So unless they specifically asked me, I didn't provide the information.

BY MR. GOTTO:

Q. Was it your intention to cooperate with law enforcement when you received inquiries of this nature?

A. To the best of my ability, yes.

Q. And did you feel that requiring them to specifically request the information before you would divulge it was cooperating to the best of your ability?

A. Yes.

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Q. You could have informed them of the information without the specific request, though, right?

MR. O'CONNOR: Objection to form.

A. If they didn't request it, I didn't know what they were looking for, and I didn't assume or presume to know what they were looking for.

BY MR. GOTTO:

Q. Did Ms. Harper -- we see her e-mail in response. Apart from her e-mail, did she ever communicate with you with respect to your practice of how to respond to law enforcement inquiries as you describe it in that first paragraph?

A. I don't understand the question.

Q. Sure.

You describe in your first paragraph of your June 17th e-mail how you handled inquiries from law enforcement, and this point of not divulging information unless specifically requested. Did Ms. Harper ever respond to you with respect to that practice to say either it was the right way to handle the inquiries or to

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suggest some other way to handle them?

MR. O'CONNOR: Objection to form.

A. So those were conversations with our legal department.

MR. O'CONNOR: And of course, I instruct the witness not to answer to the extent it gets into conversations with legal.

BY MR. GOTTO:

Q. Okay. So -- and you can just answer this yes or no. Apart from conversations with legal counsel, did you ever have any conversations with Ms. Harper on this topic of how you responded to inquiries from law enforcement of the type you describe in this paragraph?

A. Not that I remember.

Q. And again, apart from conversations with counsel, did you have discussions with anyone else at Mallinckrodt with respect to how you responded to law enforcement inquiries as you describe in this paragraph?

A. With the security director at this time.

Q. And who was that?

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A. Bill Ratliff.
Q. And what can you recall of that conversation?
A. Basically as I previously stated, we don't assume what they're looking for, we don't know the facts of their case, and we answer the questions to the best of our ability. But we don't always know who we're talking to over the phone, so if they are looking for detailed information or want documentation they have to send a subpoena so that it goes through the proper channels.
Q. Okay. And did Mr. Ratliff give you any feedback as far as that approach, either confirming it or suggesting a change?
A. I was cautioned not to give out information over the phone because we don't know who we're talking to over the phone.
Q. The practice that you described regarding when you would give information, when you would require a subpoena, was there a written policy in place at Mallinckrodt to that effect?
A. I don't believe there's a written

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policy. I believe it was through verbal training.
Q. And who gave you that verbal training?
A. Our legal department.
Q. Okay. You can set that aside.
(Whereupon, Mallinckrodt-Spaulding-31 was marked for identification.)
BY MR. GOTTO:
Q. Exhibit 31 is a multi-page e-mail thread bearing Bates MNK-T1_0005424123. These are e-mails from July of 2011. There were several e-mails here. I have a couple of questions for you really on the first page.
(Witness reviewing document.)
A. Okay.
Q. Do you recognize those e-mails?
A. I vaguely recall them, yes.
Q. Okay. What do you recall about them?
A. This was in the time that we were stopping shipments to Masters and putting their account on hold, and there was a system error in which some material that was shipped was not supposed to be.
Q. Okay. And how was that error

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uncovered, do you recall?
A. The customer called us and said they had received C2 product.
Q. Okay. And who was Brenda Rehkop? R-E-H-K-O-P.
A. Customer service rep.
Q. Were you able to determine how it came to be that the product was shipped to Masters after they had been put on hold?
A. It was a timing thing. There was an order picked and packed in the warehouse already at the time that customer service was notified to put the orders on hold.
Q. So on the first page of the exhibit, your e-mail dated July 13, 2011, you say "I completely understand and will not disclose. It's impossible to manage so many accounts manually due to these circumstances that are beyond our control."
What were you referring to there in terms of being impossible to manage so many accounts manually?
A. So it was an assumption on my part that they have multiple accounts in which

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they're releasing orders daily for clinics, because at this time we shipped clinic orders same day. They had orders that were coming in. This was at the time that there was action going on, I believe, with KeySource and Masters at the same time, and we were trying to stop orders in transit because the ISO had been issued. And there was just multiple balls in the air juggling all at one time, and this one order fell through the cracks.
Q. When you say that the order fell through the cracks, were you able to ascertain who had authorized the shipment to be made?
A. Yes.
Q. And who was that?
A. It was a CSR who released the order.
Q. And who was it?
A. Cheryl Nelson.
Q. Were there any changes made to practices or policies to assure that this sort of mistake wouldn't happen in the future?
A. Yes.
Q. What were they?
A. So instead of the customer service rep

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changing -- being able to change the credit limit to prevent it from shipping, that now has to be done by a separate department that manages the customer accounts, taking that responsibility off from the CSRs.

Q. Do you recall in any of the DEA-sponsored seminars or Buzzeo programs that you attended discussions regarding the involvement of either customer service personnel or sales personnel in the suspicious order monitoring program?

MR. O'CONNOR: Objection to form.

A. I recall at a Buzzeo conference them saying that it's not in the best interest of a company for finance people to be involved in SOM perspective to eliminate that optic of impropriety.

BY MR. GOTTO:

Q. Okay. And do you recall any similar observation you made with respect to involvement of sales personnel in SOM?

A. No, because we have to rely on sales personnel to provide us information sometimes.

Q. You can set that aside.

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(Whereupon, Mallinckrodt-Spaulding-32 was marked for identification.)

BY MR. GOTTO:

Q. Exhibit 32 is a two-page e-mail thread with the numbers MNK-T1_0000282686, e-mails from March of 2011 concerning suspicious order monitoring. Tell me if you recognize those e-mails.

(Witness reviewing document.)

A. Yes.

Q. So the earliest e-mail in the thread is from a David Picciano to Karen Harper.

And do you know who Mr. Picciano know was?

A. Yes.

Q. Who was he?

A. He's the director of regulatory compliance for Cedardale.

Q. Okay. And he says this in his e-mail, "Cedardale Distributors...is willing to comply with Covidien's request that we refrain from selling Mallinckrodt's 15-milligram and 30-milligram oxycodone tablets to the Florida based pharmacies listed on Attachment 1,"

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correct?

A. Yes, based on this e-mail.

Q. So had Mallinckrodt requested of Cedardale that Cedardale refrain from selling to specific identified pharmacies?

A. Based on this e-mail, yes.

Q. Okay. You don't independently recall that?

A. No.

Q. Do you recall there being other situations in which Mallinckrodt made requests of its distributors not to sell to particular indirect customers?

A. No.

Q. And then Mr. Picciano goes on to provide information regarding Cedardale's SOM program, correct?

A. Yes.

Q. And this appears to be before you conducted the on-site audit, correct?

A. Yes.

Q. And in your March 23rd e-mail to Ms. Harper, you say you reviewed the attached documents, "continue to believe Cedardale needs

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more work around their SOM program."

So was your e-mail prior to the on-site audit?

A. My e-mail, no. My e-mail was after their audit in which he sent me those SOPs. Because when we were there for the audit we advised him that he might want to look at making them more robust.

Q. Okay. So the SOPs are -- is that what's referenced in -- are you making reference to what's in the November 15th e-mail?

A. No. So if you look at the subject line, you can tell it changes with the March, 2011 e-mail from my e-mail to Karen with a CC to Rich.

Q. Okay.

A. And that's where I'm sending her the SOPs that David Picciano has sent to me.

Q. I see. Okay.

And at that point you concluded that their SOM program was still insufficient, correct?

A. Still weak, yes.

Q. All right. You can set that aside.

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(Whereupon, Mallinckrodt-Spaulding-33 was marked for identification.)
BY MR. GOTTO:
Q. Exhibit 33 is a one-page document, MNK-T1_0000290887, additional e-mails relating to the Cedardale audit, and these are in January of 2011.
A. Yes.
MR. O'CONNOR: Counsel, I apologize, can we go off the record for a minute?
MR. GOTTO: You bet.
THE VIDEOGRAPHER: The time is 3:35 p.m., we're off the record.
(Off the record discussion.)
THE VIDEOGRAPHER: The time is 3:36 p.m., and we're on the record.
(Whereupon, Mallinckrodt-Spaulding-34 was marked for identification.)
BY MR. GOTTO:
Q. Exhibit 34 is a one-page e-mail thread, MNK-T1_0003044340. Take a moment to look at those e-mails, if you would, and tell me if you recognize them.
(Witness reviewing document.)

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A. Okay.
Q. Do you recognize those e-mails?
A. I don't remember them, no.
Q. Okay. Who is Kenneth Yamashita?
A. He was a site director at the time.
Q. Okay. In your June 20th e-mail you say "I briefed Clay on the situation on your absence."
Who was Clay?
A. Clay Wagner was the plant controller, so he was the designee when Ken Yamashita was out of the office.
Q. The last sentence of that paragraph says "We have been asked to provide information on our Suspicious Order Monitoring Program and how it relates to quota and ties in with St. Louis plant manufacturing quota."
What was that information? How did the SOM program relate to quota and tie in with the St. Louis plant manufacturing quota?
MR. O'CONNOR: Objection to form.
A. So we explained to DEA, we hosted them on-site, and we explained to them the quota process at a high level, because DI White was

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unfamiliar of the inner workings of quota, and we explained how St. Louis plant receives manufacturing quota, we receive procurement quota, and that our quota ultimately turns into product that we send to the market.
BY MR. GOTTO:
Q. Okay. So how did the suspicious order monitoring program relate to that?
A. So I can't assume what DEA wanted to know or how it ties in. We could just explain our program.
Q. Okay. I'm just -- since this is your e-mail, I'm just wondering when you said "provide information on the SOM and how it relates to quota," was there information that comes to your mind as being -- that you provided in response to that request?
A. I don't remember specific information that was provided or if there was a presentation, only that we explained the quota process and we reviewed our suspicious order monitoring program, and that we can't ship anything to the market that we haven't been granted quota for.

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Q. Okay. So Mr. Yamashita then responds to you "Great. Thanks for the update. Did you get the impression now that if our quota justification and suspicious order monitoring program is good, we will get the quota or at least some portion?"
Do you remember what your answer to that was?
A. No.
Q. So Mr. Yamashita seems to be at least questioning whether -- or inquiring into whether the quality of the suspicious order monitoring program could have an effect on the DEA's decision as to quota to grant, is that how you understand his e-mail?
MR. O'CONNOR: Objection to form.
A. I don't know what his thoughts were at that time.
BY MR. GOTTO:
Q. Okay. Was it your belief at this time, or has it been at any time, that the DEA would be more likely to grant a quota request if it were persuaded that the suspicious order monitoring program was of high quality?

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A. No. Ken Yamashita was new to the plant at that time, he was probably just learning about how it works and what the expectations are.
Q. Okay.
(Whereupon, Mallinckrodt-Spaulding-35 was marked for identification.)
BY MR. GOTTO:
Q. Exhibit 35 is a multi-page e-mail thread, MNK-T1_0000283719. These are e-mails from 2011 regarding quota requests. If you'd take a look at them for just a moment, please. My particular question is on the e-mail that's on the second page.
(Witness reviewing document.)
A. Okay.
Q. Do you recognize these e-mails?
A. Vaguely.
Q. Okay. So the e-mail at the bottom of the first page onto the second page, is that from Frank Sapienza?
A. No, so that's the bottom -- I'm sorry, bottom e-mail of the first page?
Q. Yes, the one that starts "Hi Karen."

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A. Yes. What we referred to earlier in which they have to go for additional signatures.
Q. Okay. And then on the second page, the material in the middle that starts with "One of our industry colleagues forwarded" --
A. Yes.
Q. -- who is it that was sending that e-mail?
A. I have no idea. Oh, sending it, that's Karen.
Q. Okay. And so this is information that Ms. Harper received from someone else in the industry in June of 2011, correct?
A. That's my understanding of this, yes.
Q. Okay. And so in this -- on these eight points, the fifth point is "External review 3: The suspicious order monitoring group reviews and makes sure our material is not being used to complete suspicious orders."
Do you have an understanding as to who the suspicious order monitoring group is that's referred to in that item?
A. No, because this is pulled from somebody else in industry.

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Q. Do you know if it's a group at the DEA?
A. I don't.
(Whereupon, Mallinckrodt-Spaulding-36 was marked for identification.)
BY MR. GOTTO:
Q. Exhibit 36 is a two-page document beginning at Bates MNK-T1_0006055924. It appears to be an e-mail exchange in August of 2012 concerning safety stock. Tell me if you recognize those e-mails, please.
(Witness reviewing document.)
A. Okay.
Q. Do you recognize those e-mails?
A. No.
Q. Okay. There is -- the e-mail in the middle of the first page from you to Kevin Hewlett -- first of all, who is Kevin Hewlett?
A. He was the corporate planning manager at the time.
Q. Okay. You make reference to a formula that was used in favor of the most recent several requests. Is the formula the formula that's in the attachment?

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A. Yes.
Q. And is this what you discussed -- you testified to, I think this morning, regarding quota formula?
A. Yes.
Q. So this was the formula that was used back in 2012?
A. Yes.
Q. Has the formula changed since that time?
A. No.
Q. Okay. You can set that aside.
(Whereupon, Mallinckrodt-Spaulding-37 was marked for identification.)
BY MR. GOTTO:
Q. Exhibit 37 is a one-page e-mail, MNK-T1_0006056192. This appears to also be the quota formula. Could you take a look at that and confirm that for me?
A. Yes. Correct.
Q. Okay. You can set that aside.
(Whereupon, Mallinckrodt-Spaulding-38 was marked for identification.)
BY MR. GOTTO:

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Q. Exhibit 38 is a multi-page e-mail thread, MNK-T1_0005641401. Again, these are e-mails concerning quota. And my questions for you concern Ms. Johnson's e-mail at the bottom of the first page.
A. Okay.
Q. She says "Yes, you have it straight. Part of the difference is the formulas are in AA and the quota analysis is in Salt."
What does that mean, AA and salt in this context?
A. So AA is anhydrous alkaloid, and that's how quota is measured by, the base content. So our analysis, because we receive API in its salt form isomer on the dock, our analysis and what we track is all in salt form. But when we have to request quota from the DEA, we have to convert it back to AA, and every molecule has its own conversion factor to go from salt to AA.
Q. Okay. You can set that aside.
(Whereupon, Mallinckrodt-Spaulding-39 was marked for identification.)
BY MR. GOTTO:

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Q. Exhibit 39 is a two-page e-mail beginning at Bates MNK-T1_0007729523, appears to be an e-mail that you sent to Donald Lohman, L-O-H-M-A-N.
Who is Mr. Lohman?
A. He's our legal counsel.
Q. Okay.
MR. O'CONNOR: Counsel, maybe now is a good time for a break.
MR. GOTTO: Sounds like it might be.
THE VIDEOGRAPHER: The time is 3:49 p m., and we're off the record.
(Whereupon, a recess was taken.)
THE VIDEOGRAPHER: The time is 4:04 p m., and we're on the record.
MR. GOTTO: Counsel?
MR. O'CONNOR: All right. Counsel, thank you for that break.
Just to clarify what's transpired here, with respect to Exhibit 33, that document was clawed back pursuant to a November 27, 2018 letter, so we have just gone ahead during the break and replaced the unredacted, clawed back version with the redacted version.

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And with respect to Exhibit 39, we are now making a clawback request with respect to that because this document is protected by the attorney/client privilege as well as the work product protection, and we'll be following up with a letter shortly.
MR. GOTTO: Okay. And as to 39, that's the entire document?
MR. O'CONNOR: That's correct.
MR. GOTTO: Okay. Fair enough.
BY MR. GOTTO:
Q. Ms. Spaulding, if you'd take the redacted Exhibit 33 that you now have in front of you, I do have a couple questions for you on that. And this is Bates MNK-T1_0000290887. Take a look -- it's a one-page e-mail thread. Take a look at that, if you would, and tell me if you recognize it.
A. Yes.
Q. And so your e-mail to Mr. Nikolaus on January 14 of 2011 indicates that you "just got off a Suspicious Order Monitoring Steering Committee conference call discussing the SOM audits. I sent Karen the preliminary report

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awaiting any comments from you. Basically the committee has decided to release Masters and KeySource to resume shipping Oxy 15-milligram and 30-milligram when we come out of backorder, but has determined based on our audit that Cedardale does not have a robust enough system in place to resume shipping C2s to them." Correct?
A. Yes.
Q. Do you recall that decision by the committee?
A. Based on this e-mail, yes.
Q. So you don't have an independent recollection of what the basis was for the decision to release Masters and KeySource at this point?
A. No.
Q. Okay. You can set that aside.
(Whereupon, Mallinckrodt-Spaulding-40 was marked for identification.)
BY MR. GOTTO:
Q. Exhibit 40 is a two-page document, MNK-T1_0006442504, appears to be an e-mail from you to Richard Nikolaus dated July 17th of 2008

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attaching a letter to Denise Jordan at DEA. Take a moment and tell me if you recognize that e-mail and the attachment.

A. I don't recognize the e-mail, but it is one of my letters.

Q. Okay. So in your e-mail you say "Rich, Take a look when you get a chance and let me know what you think. I'm running out of BS to put in these letters, especially this one."

And then the letter is to Denise Jordan at the DEA.

Who was Denise Jordan?

A. She was the diversion investigator responsible for our site at that time.

Q. And so your letter is in response to an inquiry you received from her, is that right?

A. No, this is attached filing a 106. So we had a loss in transit, and this is notification to DEA of the details regarding the loss in transit.

Q. Okay. So judging from your cover e-mail where you say "I'm running out of BS to put in these letters," was there something in the Denise Jordan letter that you were referring

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to in particular by that phrase?

A. No, I was -- it was a poor choice of words basically. I was running out of explanations to explain why FedEx had lost another package.

Q. And is that because there had been a large number of incidents like that?

A. I don't know how many there had been during this specific time frame.

Q. So were there other communications -- when you say "to put in these letters," by "these letters" you mean letters to the DEA dealing with a loss incident?

A. Yes. Because FedEx would give us very little information, so we were, you know, trying to be factual in what we put to DEA, but DEA would sometimes push back and say, well, what is FedEx doing about it? And we'd go to FedEx and say, what are you doing about it? And they'd say, that's an internal investigation, we can't disclose an internal investigation, we can't disclose an internal investigation. So as -- we were caught between a rock and a hard place.

Q. Okay. You can put that aside.

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(Whereupon, Mallinckrodt-Spaulding-41 was marked for identification.)

BY MR. GOTTO:

Q. Exhibit 41 is a copy of the Administrative Memorandum of Agreement between Mallinckrodt and the DEA from 2017. Take a look at that document, if you would. First tell me if you've seen it before.

A. Yes.

Q. Okay. Are you familiar with it?

A. Yes.

Q. When did you first become aware that the DEA was formally investigating Mallinckrodt?

A. During the 2013 inspection.

Q. Okay. Did you receive copies of subpoenas that were issued by DEA in 2011 and 2012?

A. I've received copies of subpoenas. I don't remember if they were 2011 or 2012.

Q. Okay. But you recall in 2013 becoming aware of the investigation?

A. Yes, because of the audit that was conducted in March and April of 2013.

Q. Okay. And what was it about that

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audit that made you become aware of the investigation?

A. They had 15 to 16 agents and were there for 6 weeks, which was unprecedented to any other audit that had ever been done previous to that.

Q. So in previous audits, approximately how many people would be there and for approximately how long?

A. Two to four days and less than a week -- sorry. Two to four people, and there less than a week.

Q. Okay. Did you provide any sworn testimony to DEA as part of your investigation?

A. Sworn testimony, no, I don't believe so.

Q. Okay. No affidavits, anything like that?

A. There was an inspection report that was signed. There was legal documents provided. But I don't recall signing anything.

Q. Okay. You do recall receiving a subpoena from the DEA at some point, correct?

A. Yes, I received them frequently for

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shipping verifications.
Q. Okay. And do you recall receiving a subpoena that you understood to be in connection with the DEA's investigation of Mallinckrodt?
A. No.
Q. Were you aware of anyone else at Mallinckrodt giving a deposition or sworn statement to the DEA in connection with its investigation of Mallinckrodt?
A. Not that I was aware of, no.
Q. Did you have any involvement in the discussions between Mallinckrodt and DEA that led up to the memorandum of agreement?
A. Yes.
Q. What discussions were you involved in?
A. So we were -- we went to Albany DEA and met with them to review the mass balance records after they had taken copies of all of the batch records that were part of the audit. There was follow-up questions from DEA regarding the reports that we had provided, so those were all answered. That was my direct involvement with DEA.
Q. What are the mass balance records?

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A. So that's how DEA does an audit of a manufacturer. They basically take your year-ending inventory, add in all your acquisitions, and subtract out all your dispositions.
Q. And the review that you participated in with the Albany DEA, what was the focus of that review?
A. They audit three major molecules and all products produced within 14 months of oxycodone, hydrocodone, and Methadone.
Q. Did that review disclose any discrepancies?
MR. O'CONNOR: Objection to form.
A. I don't know. DEA never provides us reports, so I don't know what they came up with.
BY MR. GOTTO:
Q. Did you review a draft of the administrative memorandum of agreement before it was signed?
A. Yes.
Q. And what was the purpose of your review?
A. Because I was the key person at the

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Hobart site making sure that anything we agreed to was feasible to manage and manageable.
Q. Okay. On the first page of the administrative memorandum of agreement, there are a number of numbered paragraphs under "Background."
Do you see that?
A. Yes.
Q. And do you recall reviewing those paragraphs when you reviewed a draft of this document?
A. Yes.
Q. And was there any inaccuracy in any of those paragraphs that you can recall from your review?
A. Not that I recall.
Q. In Paragraph 2 it indicates that "From January 1, 2008, through September 30, 2011, there was an epidemic increase in diversion of the controlled substance oxycodone, largely out of the State of Florida."
Do you see that?
A. Yes.
Q. Was that a circumstance you were aware

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of during the time period January 1 of '08 through September 30th of 2011?
A. I don't know if I was aware of it at that time or not.
Q. Paragraph 3 indicates that "The United States alleges that Mallinckrodt, a manufacturer and distributor of oxycodone, knew about the diversion and sold excessive amounts of the most highly abused forms of oxycodone, 30-milligram and 15-milligram tablets, placing them into a stream of commerce that would result in diversion."
Did you believe that that allegation was accurate when you reviewed a draft of this document?
A. No.
Q. What parts of it do you think were inaccurate?
A. That we knowingly sold excessive amounts.
Q. Okay. Paragraph 4 indicates that "Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these

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sales and report suspicious orders to DEA."
Did you believe that was accurate when you reviewed it?
A. Yes.
Q. Paragraph 5, the last sentence states "Furthermore, the United States alleges that Mallinckrodt never notified the DEA of the suspicious orders in violation of the CSA."
Did you believe that statement was -- or that that allegation was accurate when you reviewed a draft of this document?
A. No.
Q. If you'd turn to Paragraph 3 on Page 2 of the document, Paragraph 3(a) states that "With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 CFR Section 1301.74(b)."
Did you believe that the allegations

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described in that sentence were accurate when you reviewed a draft of this document?
A. The alleged allegations, yes.
Q. You understand --
A. Wait a minute. I'm sorry, I don't understand.
Q. You understood it was accurate that those allegations were made. My question is, did you believe that the underlying allegations were accurate?
A. No.
Q. And in what regard did you believe they were not accurate?
A. We were reporting any orders that we deemed to be truly suspicious, and I don't believe that we failed to report any suspicious orders. And although there's allegations and we settled with the MOA, we didn't admit any wrongdoing.
Q. And under paragraph A, there's specific -- in the Roman Numeral numbered paragraphs, number "i. conduct adequate due diligence of its customers."
Do you believe that Mallinckrodt did

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conduct adequate due diligence of its customers?
A. Yes.
Q. And do you believe -- under Roman Numeral ii, do you believe that Mallinckrodt detected and reported to the DEA orders of unusual size and frequency?
A. What is an order of unusual size and frequency? I mean, yes, we did the best with the information we had.
Q. You understood that there was a regulatory obligation to report orders of unusual size and frequency, correct?
A. Yes.
Q. The next paragraph, "detect and report to the DEA orders deviating substantially from normal patterns."
Again, you understood that there was a regulatory requirement to detect and report such orders, correct?
A. Yes.
Q. And do you believe Mallinckrodt did so?
A. Yes.
Q. Paragraph iv, "use 'chargeback' information from its distributors to evaluate suspicious orders."
Prior to October of 2010, Mallinckrodt did not use chargeback data as part of its SOM program, correct?
A. No, it's not part of the regulations.
Q. And Roman Numeral v, "take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers."
Do you believe that Mallinckrodt was under an obligation to take action to prevent recurrence of diversion in these circumstances?
MR. O'CONNOR: Objection to form.
A. Not under the regulations, but as part of our MOA, yes.
BY MR. GOTTO:
Q. Paragraph B has a series of allegations regarding the Hobart facility, correct?
A. Yes.
Q. And these are matters that you have some personal familiarity with, correct?

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A. Yes.
Q. And so paragraph "i. failure to take actual weights of controlled substances at all stages of the manufacturing process."
Did you feel that was an accurate allegation?
A. Yes.
Q. And what was done to rectify that situation going forward?
A. We immediately at the -- this was discovered during the 2013 audit, and so we immediately updated the records that didn't have complete weights, complete physical inventory of the entire site was taken to make sure we had a complete and accurate inventory, and we changed our receiving process to do a check-weigh on all API coming in, not just a seal verification and label verification.
Q. Okay. Paragraph ii, Roman ii, "use of a 'target' tablet weight for purposes of reconciling batch records and determining the number of units of finished form manufactured even though the actual average weight of the tablets in any specific batch sometimes deviated

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from the target weight."
Did you believe the allegation described in B(ii) was an accurate allegation?
A. Yes.
Q. And what was done to rectify that going forward?
A. Again, immediately during the 2013 audit before this MOA, we changed our procedures to calculate an actual weight per lot for each batch produced, and that actual weight per batch is now what's used in reconciliation purposes.
Q. Okay. And B(iii) related to "commingling of dust collector waste and assignment of dust losses."
Did you feel that was an accurate allegation when it was made?
A. No.
Q. What part of it did you think was not accurate?
A. Without confirming how much dust was actually attributable to any specific batch.
Q. Do you know why the DEA alleged that lack of confirmation?
MR. O'CONNOR: Objection to form.

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A. Because of the way that the dust collectors operate and are designed, there is challenges with being able to account for any specific batch, but it's not a result of not trying to determine how much went into each batch.
BY MR. GOTTO:
Q. How about Roman Number iv, "failure to check-weigh controlled substances received into the facility," was that an accurate allegation?
A. Yes.
Q. What was done to rectify that?
A. As mentioned before, the check-weigh of all procedures -- of all controlled substances coming into the facility.
Q. And Roman Numeral v, "failure to maintain accurate records of substances transferred from the manufacturing process to Mallinckrodt's analytical laboratories," did you think that was an accurate allegation?
A. Yes.
Q. And what was done to rectify that?
A. So there was a gap in our record receiving documents within the laboratories, and

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again during the 2013 audit, it was -- DEA had detected that, and we immediately updated our documents to have traceability of all samples coming into the lab regardless of their controlled substance schedule.
Q. Okay. And Roman Numeral vi, "failure to include substances held in certain vaults/storage as part of the biannual inventory, and records provided for vaults containing discrepancies with respect to weight, missing substances, incorrect lots/batch numbers, and incorrect or incomplete drug names." Did you believe that was an accurate allegation when it was made?
A. Yes.
Q. And what was done to rectify that?
A. That was part of the complete physical inventory that was taken that same time period of counting and documenting every single controlled substance in the facility.
Q. So the various allegations under paragraph B that you've indicated you believed were accurate allegations when they were made, were those circumstances that came into

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existence during 2013?
A. Came, like had just started?
Q. Yes.
A. No.
Q. Okay. Do you have any idea when they did start?
A. No, that's just when they were detected.
Q. And what caused them to be detected?
A. Part of the audit that the DEA conducted.
Q. And do you know what was different in the 2013 audit that gave rise to that detection that hadn't caused these circumstances to be detected previously?
A. In the 2000 DEA -- 2013 DEA audit, there was more investigators there, and they were going through the batch records in greater detail than they had in any previous audit.
Q. Okay. Paragraph 4 states it is not an admission of liability, however, Mallinckrodt agrees that at certain times certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards

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outlined in letters from the DEA deputy administrator from September and December of 2006 and 2007 respectively.
Do you see that?
A. Yes.
Q. And do you believe that's true, that certain aspects of the SOM program in place at Mallinckrodt prior to January 1, 2012 did not meet standards outlined in those letters?
A. Do I personally?
Q. Yes.
A. No, I believe they did.
Q. Do you know why Mallinckrodt agreed that the SOM did not meet certain of those standards?
A. I do not.
Q. Did you have any discussions with anyone at Mallinckrodt prior to the time this memorandum of agreement was executed with respect to that point?
A. I remember having discussions. I don't know if it was part of the memorandum of agreement that we were doing the best we could with what we had and the direction we had been

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given.
Q. Did you ever receive any performance evaluation that -- well, strike that.
In any of your performance evaluations that you received at Mallinckrodt, was the subject of the suspicious order monitoring program one of the items on which you were evaluated?
A. Yes.
Q. And what evaluations did you receive in that regard?
A. I was always meeting expectations.
Q. And who was it who performed your evaluations?
A. My manager.
Q. Ms. Harper?
A. Yes.
Q. You were familiar with the DEA letters from September of '06 and December of '07 that are referred to in Paragraph 4, correct?
A. Yes.
Q. So if, in fact, aspects of Mallinckrodt's SOM program did not meet the standards outlined in those letters, that

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failure would have indicated, at least to some extent, a personal failure on your regard -- on your part with respect to the SOM program, right?
MR. O'CONNOR: Objection to form.
A. I don't think I understand. Are you saying that because we admitted that our program wasn't robust I wasn't doing my job?
BY MR. GOTTO:
Q. Well, let me put it a little differently.
During the period prior to January 1 of 2012, did you attempt to cause the SOM program at Mallinckrodt to be in compliance with the standards outlined in the DEA letters of September of '06 and December of '07?
A. I believe I did, yes.
Q. Okay. And so if, in fact, the program was not in compliance with those standards, then that would have meant that you failed to achieve your objective in that regard, correct?
MR. O'CONNOR: Object to form.
A. I disagree with that.
BY MR. GOTTO:

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Q. You disagree with whether the program met the standards, right?
A. No, I disagree with whether I was doing what was expected of me and met the intent of the letters based on the information and the direction that we have. DEA gives very little guidance around what is an unusual order, what is a suspicious order, so we have to interpret that the best that we can, and I feel that I've done that.
MR. GOTTO: Okay. Why don't we go off the record.
THE VIDEOGRAPHER: The time is 4:34 p.m., and we're off the record.
(Whereupon, a recess was taken.)
THE VIDEOGRAPHER: The time is 4:45 p.m., and we're on the record.
EXAMINATION
BY MR. GESTEL:
Q. Good evening, Ms. Spaulding.
MR. GESTEL: Before I begin, I'll just launch what has become our standard objection without going into the whole basis for that, if you'll let me. I assume that you'll --

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MR. O'CONNOR: I'll offer our standard objection to the objection.
MR. GESTEL: All right. Thank you.
BY MR. GESTEL:
Q. Ms. Spaulding, my name is Ben Gestel. I represent a group of plaintiffs in the State of Tennessee that are in a slightly different lawsuit than the lawsuit that Mr. Gotto was asking you questions about this morning.
I'll begin by asking you, have you reviewed the complaint in any of the Tennessee cases?
A. No.
Q. I'm going to also sort of back up and do a couple of preliminary things.
Where do you live? What is your residential address?
A. [redacted]
Q. And how long have you lived there?
A. 12 years.
Q. And who lives there with you?
A. Currently alone.
Q. And then do you have any plans to move

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any time soon?
A. Not that I foresee.
Q. And then, if this was covered this morning I apologize, but can you do a -- provide some -- a little bit of your educational background?
Did you graduate from college?
A. Again, I have an associate from BYU in computer information systems.
Q. When you say BYU, is that Brigham and Young University?
A. Yes, the Idaho campus.
Q. And how long ago did you receive that degree?
A. 1990.
Q. And were you living in Idaho at the time?
A. While I attended college. No, I lived in New Jersey, went to college in Idaho, and came back to New Jersey.
Q. Got it. Thank you very much.
And what is your current title at Mallinckrodt?
A. Controlled substances compliance

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manager.
Q. And in that role do you have supervisory authority over any employees?
A. Yes, I have two employees on my team.
Q. Who is directly reporting to you?
A. Carrie Johnson and Rachelle Rogers.
Q. And if I'm understanding the testimony earlier, are you continuing to directly report to Karen Harper?
A. I am.
Q. In your work with Mallinckrodt, did you have occasion to travel to the State of Tennessee?
A. I have attended a conference in Tennessee.
Q. Do you remember what conference that was?
A. NADDI conference in Nashville.
Q. Do you remember what year that was?
A. Not the exact. It's within the past five years.
Q. Apart from attending that NADDI conference in Nashville, do you recall ever travelling to the State of Tennessee for your

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work for Mallinckrodt?
A. No.
Q. So you don't ever recall travelling to a distributor's facility in Tennessee to do an audit?
A. I stand corrected. I have travelled to Memphis in my role at Mallinckrodt to FedEx. And I've been to a distributor -- no, they're not in Tennessee, sorry. Just FedEx in Memphis, Tennessee.
Q. And do you recall when it was you went to FedEx?
A. Not exactly. I've been there three or four times.
Q. When was the most recent trip that you were there?
A. It's been many years.
Q. And can you just provide a general overview of what you were doing at that FedEx facility?
A. We were doing a collaboration visit. They gave us a tour of the facility. We were conducting an audit because we had had some losses in transit with FedEx, and reviewing

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their security procedures and how they handle Mallinckrodt freight when it goes through the hub.
Q. And was this before the transition over to the FedEx Express service that you talked about this morning?
A. It was after.
Q. It was after that.
And you said "we went." Do you recall who went with you?
A. Security managers, Rich Nikolaus.
Q. Anybody else attend on that trip?
A. No, not that I can recall.
Q. As you sit there today, do you have any understanding of opioid prescription rates in the State of Tennessee?
A. No.
MR. O'CONNOR: Objection to form.
BY MR. GESTEL:
Q. I think you testified earlier that you believe that there's a current opioid epidemic going on in this country, is that correct?
MR. O'CONNOR: Objection.
A. I'm aware of it.

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BY MR. GESTEL:
Q. And are you aware that epidemic is particularly acute in some parts of the country compared to other parts of the country?
MR. O'CONNOR: Objection to form.
A. Yes.
BY MR. GESTEL:
Q. Do you believe that Tennessee has been particularly hard-hit by the opioid crisis?
MR. O'CONNOR: Objection to form.
A. I don't know how significant or hit any one state is over another.
BY MR. GESTEL:
Q. Sure.
But do you understand or do you believe that Tennessee has -- is one part of those country -- one part of this country that has been particularly hit by the opioid epidemic?
MR. O'CONNOR: Objection.
A. I'm aware that Tennessee has concerns. I don't know the specific facts to know whether it was one of the highest or not or more so than any other state.

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BY MR. GESTEL:
Q. Do you recall during your time with Mallinckrodt ever discussing any specific pill mill operations in the State of Tennessee?
MR. O'CONNOR: Objection to form.
A. Nothing specific, no.
BY MR. GESTEL:
Q. Have you ever reviewed IMS Health data regarding the rates of prescribing of opioids related to the State of Tennessee?
A. No.
Q. Have you ever heard of Interstate 75 being described as the "Oxy Express"?
A. Yes.
Q. About when did you first hear that term?
A. Several years ago. I don't remember exactly when.
Q. And I don't mean to test your knowledge of American geography, but are you aware that Interstate 75 runs through the State of Tennessee?
A. At a high level, yes.
Q. In your role as manager of controlled

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substances, did you interact with law enforcement officials in the State of Tennessee?
A. I interact with law enforcement officials. I don't remember specifically if any of them have been from Tennessee. They could have, but I don't know specifically.
Q. Did you have occasion to ever just have a conversation with a police officer from Morristown, Tennessee? Does that ring a bell in your mind at all?
A. I believe the security director had a conversation with someone from Morristown, Morrisville.
Q. But you weren't involved in that conversation, to the best of your recollection?
A. No, not directly.
Q. How did you learn about it indirectly?
A. The security director asked me for shipping information, that he had been contacted by somebody from Morrisville, Tennessee.
Q. And then why would he contact you about that information, if you know?
A. Because I was at the distribution center and could run the reports to know what --

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where we shipped our orders to.
Q. And then did you provide him the report that he asked for?
A. Yes.
Q. And then did you follow up with him at all after providing that report about the status of that Morristown investigation?
A. No.
Q. Have you ever asked any law enforcement official about prescription opioid division -- I'm sorry, strike that.
Have you ever asked any law enforcement official where prescription opioid diversion was most prevalent?
A. No, not that I can recall.
Q. During your time with Mallinckrodt, have you ever had occasion to run reports detailing the percentage of oxycodone sales for Mallinckrodt's distributors in certain states?
A. Can you say that again?
Q. Sure.
During your time with Mallinckrodt, have you had occasion to run reports detailing the percentage of Oxy sales for Mallinckrodt's

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distributors in certain states?
A. I have not, no.
Q. I'm going to hand you a document that we'll mark as Exhibit 42.
(Whereupon, Mallinckrodt-Spaulding-42 was marked for identification.)
MR. GESTEL: (Handing). Sorry, that was a little -- like Tom Brady over here.
BY MR. GESTEL:
Q. I hand you a document that's been marked as Exhibit 42. I'll represent to you that the first page is a cover page carrying the Bates label of this Excel spreadsheet that was sent to us, and it has some what's called metadata showing that it was last modified on September 2, 2011. The reason why we do that, ma'am, is that the spreadsheet was produced to us in native format so the Bates numbers don't appear, but that's the Bates number of this document.
And if you flip to the first page, in the upper left-hand corner there is in column A1, it says "Oxy's percent of sales by state per distributor versus sales in all US by district,"

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I assume.
Do you see that?
A. Yes.
Q. Have you ever seen this document before, ma'am?
A. I don't remember if I have or have not.
Q. Do you ever recall doing any training on this document, where you might have trained people to run these reports?
A. No.
Q. Do you see that the state listed here is Florida?
A. Yes.
Q. And then flip to the next page. Do you see that the state listed there is Texas?
A. Yes.
Q. And flip to the next page. Do you see that the state listed there is Ohio?
A. Yes.
Q. And flip to the next page. Do you see that the state listed there is Kentucky?
A. Yes.
Q. And then flip to the next page. And

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do you see there that the state listed there is Tennessee?
A. Yes.
Q. And none of this is -- you don't believe you've ever seen this document before?
A. I don't remember it.
Q. And then flip to the next page. And there's the State of Georgia. Do you see that?
A. Yes.
Q. And then if you flip to the next page, there's a graph titled "Percent of Oxycodone Sales in Florida."
Do you see that?
A. Mm-hmm.
Q. Do you recall ever seeing a graph like this in your work with Mallinckrodt?
A. No, I don't remember.
Q. And do you remember why, if at all, in 2011 Mallinckrodt might have become interested in tracking oxycodone sales to the states listed in this spreadsheet?
A. Only due to DEA activities around that time period.
Q. And if you wanted to have a chart like

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this made for you, it sounds like you don't recall running these types of reports, who would you go to within Mallinckrodt in 2011, if you can recall, to run a report like this?
A. Oxy sales by state by distributor. It could have been in our finance department, or it would go to our marketing department.
Q. And who in those departments would you direct an inquiry to?
A. Whoever was the head of the department at the time.
Q. Would that have been Jen Buist?
A. No. Jen Buist would have gotten it from one of those departments.
Q. Would it have been Jen Terp?
A. Could have been. I don't know for sure.
Q. You can set that aside. Thank you very much.
(Whereupon, Mallinckrodt-Spaulding-43 was marked for identification.)
BY MR. GESTEL:
Q. I'm going to hand you a document that we'll mark as Exhibit 43.

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MS HOSMER: Do you have a Bates number for us, please?
MR. GESTEL: Sure.
MS HOSMER: Thank you.
BY MR. GESTEL:
Q. This is an e-mail carrying Bates label MNK-T1_0007898862. And then do you see that this is an e-mail dated November 26, 2013 from Jennifer Buist to you carrying a subject "KVK Heat Maps"? Did I read that correctly?
A. Yes.
Q. Do you recall this e-mail?
A. Vaguely.
Q. And then, let me put a clean copy up. And the first -- or the last e-mail in that chain says "These may be discussed during our staff meeting."
Do you see that?
A. Yes.
Q. And then a couple e-mails down is an e-mail from Julie Milford to Jacob Longenecker with Jen Terp and Jennifer Buist copied.
Do you see that?
A. Yes.

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Q. And the body of that e-mail says "Hi Jake, Attached are the heat maps with Mallinckrodt data. I also added a section on per capita usage to negate any effects or questions around population sizes. Similar patterns still exist that suggest relatively high usage in the Pacific Northwest, especially for the 5-milligram tablet. In general, there are still high rates in the KY, WV, and Tennessee area and in Florida."
Did I read that correctly?
A. Yes.
Q. And attached to this e-mail chain is this referenced heat maps, and I think it's just a PowerPoint presentation carrying the title "Volume Heat Maps."
Do you see that?
A. Yes.
Q. Do you recall ever running these heat maps while you were employed at Mallinckrodt?
A. No, I didn't run them.
Q. Do you recall this spread -- or this PowerPoint presentation as you sit here today?
A. Now that I'm looking at it, I vaguely

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remember it, yes.
Q. And then if you flip to the first page of the PowerPoint presentation, it says "MNK geographical patterns are similar to the rest of the market."
Did I read that correctly?
A. You said the first page?
Q. The first page of the PowerPoint.
A. Yes.
Q. And then there's two maps. There's a map carrying the title of "All Strengths - Mallinckrodt."
Do you see that?
A. "All Strengths - Mallinckrodt," yes.
Q. And then the second map is "All Strengths - Other Manufacturers."
Do you see that?
A. Yes.
Q. And then it appears that based on the legend here at the bottom that the deeper purple you get in an area, the more Oxy prescriptions in that area. Is that your understanding of this heat map?
A. Well, it's saying "All Strengths," so

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not just oxycodone.
Q. Okay. But regardless, as you get more purple, you see more -- that's more units going into that geographic territory, right?
A. Based on the legend.
Q. And then if you look here in the area of the country that is Tennessee, you'll see that it's -- do you see that it's purple in the areas around the State of Tennessee?
A. Yes, roughly.
Q. And then also on the Other Manufacturers map, the State of Tennessee is kind of more purple than other areas around it.
Do you see that?
A. I wouldn't say it's more purple than other areas around it, but I see it.
Q. But you would agree with me that that's a -- the State of Tennessee is purple in this graph, correct?
A. In which one, the Other Manufacturers or the Mallinckrodt one?
Q. The Other Manufacturers.
A. Yes.
Q. And then do you see here at the bottom

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it says the source is IMS, LRx, Xponent.
Do you see that?
A. Yes.
Q. And it's apparently from July, 2012 to June, 2013?
A. Yes.
Q. Do you know what the IMS, LRx, Xponent references?
A. No, I do not.
Q. Do you believe that that could be a reference to IMS Health data?
A. Reasonably.
Q. Are you familiar with IMS Health data?
A. At a very, very high level.
Q. Do you use that at all in suspicious order monitoring program at Mallinckrodt?
A. I do not, no.
Q. Do you know of anybody within the suspicious order monitoring program at Mallinckrodt who uses IMS Health data?
A. Not currently, no.
Q. Well, was it ever used, to the best of your knowledge?
A. So I know at one point in time this

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group may have had access to IMS data in which Jen Buist, who was the SOM auditor analyst at the time, may have reached out to her for information, but I don't know that and I can't speak on her behalf.
Q. And when you say "this group," what do you mean?
A. The commercial marketing. I don't even know who Ms. Julie Milford is, but her title says she's global business insights and forecasting, commercial analytics.
Q. And you're getting that from the cover of this -- the cover e-mails?
A. Yes. I don't know who she is.
Q. If you'll flip back, there's a very similar map to the one we just went through carrying the labels of "30-milligram." It's about halfway back, I apologize. These PowerPoint presentations aren't numbered. There's a 30-milligram chart.
A. Yes.
Q. And then do you see that this particular chart carries the title "Mallinckrodt and other manufacturers have very similar

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geographical dispensing patterns"? Did I read that correctly?
A. "Have very similar geographical dispensing patterns," yes.
Q. And then once again we see a map with the legend that the more purple an area is, the more 30-milligram Mallinckrodt extended units have been sent into that area.
Do you see that?
A. Based on the map, yes.
Q. And then do you see the State of Tennessee is purple once again?
A. Yes.
Q. If you flip to the next page, there's a -- it carries the title of "Per Capita Heat Maps."
Do you see that?
A. Yes.
Q. And then there are similar maps to the one that we just went through. The first one listed after that cover page is the one carrying the title "The coasts have more per capita usage than the midwest."
Do you see that?

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A. Yes.
Q. And then again there's another map showing per capita Oxy usage, and it appears that the greener that you get in this map the more per capita usage you see.
Do you see that?
A. Based on the map, yes.
Q. And then on the "All Strengths - Mallinckrodt," you'll see that Tennessee, and particularly East Tennessee, is green.
Do you see that?
A. I don't know exactly where Tennessee starts and ends, but --
Q. Well, if you go over to the "All Strengths - Other Manufacturers," the outline of the State of Tennessee is a little bit more prevalent there in the southeast portion of the country.
Do you see that?
A. Yes.
Q. And then if you -- the area, especially the eastern portion of that area is also lit up on the Mallinckrodt All Strengths map, correct?

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A. The All Strengths - Other Manufacturers, yes.
Q. And then also on the All Strengths - Mallinckrodt map, the eastern portion of that region is also green.
Do you see that?
A. No, because I see darker green spots all throughout Tennessee.
Q. I see.
So you would agree with me that the State of Tennessee is green in the All Strengths - Mallinckrodt map?
A. It's a light shade of green, yes.
Q. And then once again if you'll flip back to the 30-milligram page, a very similar heat map showing the -- carrying the title "Per capita usage of the Oxy 30 tablet is lowest in the midwest." Did I read that correctly?
A. Can you say that again, please?
Q. Sure.
The title of the 30-milligram slide is that "Per capita usage of the Oxy 30 tablet is lowest in the midwest."
Did I read that correctly?

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A. I went the wrong way.
Q. I think it's the second-to-last, or might be the very last page.
A. Last page. Got it, yes.
Q. And then once again on the Mallinckrodt 30-milligram page, we see that Tennessee is green, suggesting once again larger per capita usage.
Do you see that?
A. I can't tell where Tennessee starts and ends, but I see that there's green on the map.
Q. Sure.
And then also over here on the 30-Milligram - Other Manufacturers, you also see in the area of the State of Tennessee green, suggesting greater per capita Oxy 30 usage in the State of Tennessee, right?
A. Based on these maps, yes.
Q. And once again, not to belabor the point, but apparently the source of the per capita map is also this IMS, LRx, Xponent from July 2012 to June 2013.
Do you see that?

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A. I see it. I don't know what it is.
Q. Sure.
Do you recall using these heat maps at all in the suspicious order monitoring program?
A. I do not, no.
Q. But you don't have a specific recollection as to whether or not the suspicious order monitoring program was generating these heat maps as part of its suspicious order monitoring program?
A. Correct. Jen Buist was the analyst at the time responsible.
Q. And do you know who Jen reported to?
A. She started out reporting to Gail Tetzlaff, director of government reporting.
Q. Okay. And then at some point did that change?
A. Yes. Then she reported to Don Lohman in legal.
(Whereupon, Mallinckrodt-Spaulding-44 was marked for identification.)
BY MR. GESTEL:
Q. Same rules apply, by the way, if you need a break by all means, just say so and we

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can take a break.
A. Thank you.
Q. I can assure you I will be much shorter in my examination than Mr. Gotto was this morning, but...
I'll hand you a document that we'll mark as Exhibit 44. I do this once a deposition where I accidentally mark my copy, so just give me one second and let me flip this over. I should learn my lesson and that should be the last one that I mismark.
This is an e-mail sent on June 29, 2012 from you to Karen Harper carrying the subject line "DEA Albany/New York City Meeting notes on SOM/Quota."
Did I read that correctly?
A. Yes.
Q. And you ask Karen Harper to "review and make edits/comments as you feel appropriate. Please advise when I may publish to Ken."
Did I read that correctly?
A. Yes.
Q. Do you recall what you mean by this "publish to Ken" comment?

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A. Sent to Ken Yamashita, the site director.
Q. And he was the site director for what site?
A. Hobart.
Q. For Hobart?
A. Yes.
Q. And then if you flip over, this e-mail attaches this Word document carrying the title "Notes from Hobart Meeting with DEA Albany/NYC on SOM and Quota, 6/26/12."
Do you see that?
A. Yes.
Q. Do you recall this meeting with the DEA in June of 2012?
A. To be honest, no, I don't.
Q. And that's all right. But you see that you -- in the Mallinckrodt attendees you're listed there at the bottom, Eileen Spaulding?
A. Yes.
Q. Any reason to doubt that you were there?
A. No, no. I'm sure I was there. I just don't remember it.

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Q. And then apparently there was some question/answer between Mallinckrodt representatives and the DEA, and I want to direct your attention to the bottom of that first page of the Word document. There's a question there about "How long does it take to process lines?" Do you see that question?
A. Yes.
Q. And then the answer apparently given was "Reports are run daily at 9:00 a.m. and 3:00 Central. The average time is 10 to 15 minutes to review and process each line that has gone on hold."
Did I read that correctly?
A. Yes.
Q. Is that suggesting that processing lines, these are the orders that have been flagged by the suspicious order monitoring algorithm as needing further investigation?
A. Yes.
Q. And then the average time to process those were 10 to 15 minutes to review?
A. Each line.
Q. For each line?

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A. For each order, yes.
Q. Okay. Flip to the next page. Top of the page, the question "When you say 195 lines filed, what does it mean?" And then the answer is "It means that the line has hit the algorithm and requires review and/or investigation."
Did I read that correctly?
A. Yes.
Q. Does that suggest that there's 195 lines that are hitting the algorithm?
A. It could.
Q. And is that, do you know, or do you recall, is that 195 lines a month, a week, a day?
A. I don't know the time period that Don was speaking to.
Q. And you don't recall any specifically from this meeting?
A. No. I mean, as I testified earlier, I remember reviewing our SOM program, but I don't remember specifics of the meeting.
Q. Sure.
And then the next question there is "How many orders have been deemed suspicious?"

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Do you see that?
A. Yes.
Q. And then the answer is "None, it was explained that this updated SOM program went into place on 3/1/2012 and no orders have been determined to be suspicious since that date."
Did I read that correctly?
A. Correct.
Q. Is that consistent with your recollection that there was no suspicious order reported on the updated SOM program since it went into place on March 1st of 2012?
A. Between March 1st of 2012 and the date of this meeting on June 26th of 2012, correct.
Q. And then does that -- taking that with the previous question, does that suggest to you that the 195 lines that were flagged were in that period between June 1st -- I'm sorry, March 1st, 2012 and the date of this meeting of June 26, 2012?
MR. O'CONNOR: Object to form.
A. I don't know. I wouldn't want to guess that that is.
BY MR. GESTEL:

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Q. You can set that aside.
(Whereupon, Mallinckrodt-Spaulding-45 was marked for identification.)
BY MR. GESTEL:
Q. I'm going to hand you what's been marked as Exhibit 45. Sorry, I'm somehow down a copy.
Do you see that this is a document Bates stamped MNK-T1_0006967775, and it's carrying the title "CSC Steering Committee Meeting Notes," December 12, 2012.
Do you see that?
A. Yes.
Q. And you are on the suspicious order monitoring steering committee at that time, correct?
A. Yes.
Q. And you see that there's a reference to introducing John?
A. Yes.
Q. Do you recall who that was?
A. John Gillies.
Q. And was he just coming on board at this time?

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A. Yes.
Q. Flip to the second page. There's some bullet items there, and it says, third one down, it says "We also dropped out," and I think that's a typo, it should be "our multiplier from [redacted]."
Do you see that?
A. Yes.
Q. So does that suggest to you that in December of 2012 that the suspicious order monitoring algorithm threshold was lowered from [redacted]?
A. Yes.
Q. And then I believe that you testified earlier that eventually that was also further reduced down to [redacted]?
MR. O'CONNOR: Objection to form.
A. I don't remember stating that. I don't know that it's [redacted]. I know it went from [redacted] to [redacted] we spoke about that earlier, but I don't remember that it went from [redacted] down to [redacted].
BY MR. GESTEL:
Q. So is the multiplier currently [redacted]?
A. Yes.

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Q. And do you believe that that's been the case from December of 2012 to the present?
A. Based on my knowledge, yes.
Q. And then it has a description there, "we multiply the 18 month average of orders on a per customer, per SKU basis and multiply that amount by [redacted] to get the level at which orders will trip the volume flag that month. We do the same for number of orders."
Did I read that correctly?
A. Yes.
Q. And is that a description of how the algorithm functionally works?
A. One component of it.
Q. And so is it safe to say that once you move the [redacted] multiplier, if an order was within [redacted] times the 18-month moving average that that order would not be flagged and would be processed and shipped?
MR. O'CONNOR: Objection to form.
A. If it did not? Can you repeat that?
BY MR. GESTEL:
Q. Sure.
Is it safe to say that once you move

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the [redacted] multiplier, if an order was within [redacted] the 18-month moving average that order would not be flagged and would be processed and shipped?
A. If it was less than [redacted], yes, that's correct.
Q. And that would be the same for the number of orders, right?
A. For this frequency, order frequency, yes.
Q. And then -- and is that how the algorithm continues to operate today?
A. Yes.
Q. For both volume of order and for the number of orders?
A. Yes.
Q. And then if you flip -- continuing on that page, it ends with this reference to "Jen Buist Statistics."
Do you see that?
A. Yes.
Q. And then there's a reference to a tier 1 and a tier 2.
Do you see that?

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A. Yes.
Q. What is tier 1 and tier 2?
A. Tier 1 is the top three major distributors for Oxy 15-milligram and Oxy 30-milligram. So if there -- it's a multi-layered system. So tier 1 looks at Oxy 15 and Oxy 30s for the big three, and if the order hits the threshold amount, then it will go on a tier 1 hold. Tier 2 is based on all orders being reviewed by an 18-month history.
Q. Okay. And am I understanding your testimony correctly that only the big three distributors would be in the tier 1?
A. Yes.
Q. And just for the record, who are the big three?
A. McKesson, AmerisourceBergen, and Cardinal.
Q. And then tier 2, am I understanding your testimony correctly that that's essentially everybody else?
A. That's everybody including the distributors, but it's based on an 18-month -- including the big three distributors for all

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products, but it's based on the 18-month history. So that's where it's referring to the multiplier above.
Q. Got it.
And then do you see that there's two columns there of "Order Lines Processed" and "Order Lines Failed"? Do you see that?
A. Yes.
Q. And in tier 1, just take March of 2012, there's 124 order lines processed and 56 order lines failed.
Do you see that?
A. Mm-hmm.
Q. So does that mean that in March of 2012, for tier 1 orders there were 124 of them?
A. There were 124 orders processed. 56 went on hold.
Q. And that means that it flagged the algorithm?
A. Yes.
Q. Do you recall what was going on in March of 2012 to suggest that high level of flagging by the algorithm?
A. I don't. I know it's when the program

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started, so I don't know if there was historical data that needed to be loaded.
Q. Sure.
A. Or I don't remember specifically.
Q. And then you see for the rest of the tier 1, that March of 2012 is an anomaly? Would you agree with me with that?
A. Yes.
Q. So -- and then there's less orders processed going down the line, and then correspondingly less order fails, correct?
A. Correct.
Q. And again, that's the number of those orders that are being flagged by the algorithm, right?
A. Correct, for tier 1.
Q. So if you just look at the averages here, you take an average, and it does the math for you there, 78 average orders during that time period, on average 7 monthly fails.
Do you see that?
A. It's 78 lines, not 78 orders.
Q. Sorry. Thank you.
78 lines, 7 line fails, right?

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A. Yes.
Q. And just simple math, that suggests that 90 percent of the orders are making its way through the algorithm and being processed and shipped, right?
A. If they don't hit tier 2 metrics, yes.
Q. Sure.
And then down on tier 2, it has the same two columns, Order Lines Processed, Order Lines Failed, right?
A. Yes.
Q. I don't want to belabor the point, but again, these are lines that go through the algorithm in tier 2, correct?
A. Mm-hmm. Sorry, yes.
Q. And then order lines failed are those that are flagged by the algorithm for additional investigation?
A. Yes.
Q. And then again taking the averages here, the sheet does the math for you, that's on average per month 8,436 lines on average are processed per month, correct?
A. Yes.

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Q. And then 596 average order lines hitting the algorithm, right?
A. Yes.
Q. And so that's approximately, just doing the math, about 93 percent clearing the algorithm and being processed and shipped, right?
A. Yeah, I don't know the math, but -- not my thing.
Q. And do you know, apart from sort of that March, 2012 anomaly, do these statistics hold from 2012 to the present, do you know?
A. I don't, not without running reports and looking at them.
Q. And I assume that, again, based on the document here, that Jen Buist must have ran these statistics?
A. She did when she was in that role.
Q. And it sounds like she's no longer in that role?
A. Correct.
Q. Who is in that role?
A. Rachelle Rogers.
Q. Do you know if the SOM steering

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committee is continuing to receive these types of reports showing how many tier 1 and tier 2 order lines are being processed and hitting the algorithm?
A. Not recently.
Q. And then we saw in the previous document that when that investigation gets tripped, the investigation takes 10 to 15 minutes, right?
A. On average.
Q. And is that continuing the average from 2012 to the present?
A. I'd have to run reports. It's -- every line is thoroughly investigated.
Q. And who would you go to to run that report about how long it's taking to process the orders that are being hit by the algorithm?
A. I would run it.
Q. You would run the report?
A. Mm-hmm.
Q. How would you do it?
A. We have a system. Well, let me clarify.
So how long it takes to review, to

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review and release an order if appropriate?
Q. Yes.
A. So I don't know that we'd have a mechanism to know that. It's human involvement, and I have an analyst that that's what her full-time job is, and she spends a good part of her day reviewing and releasing, so I don't -- we don't have a mechanism that tracks exactly how long it takes.
Q. And who is that analyst?
A. Rachelle Rogers currently.
Q. And how long has she been in that role?
A. Since December.
Q. And did she take over from Jennifer Buist?
A. No. She took over from Amanda Chase who was in that role for approximately a year and a half.
Q. And did Amanda Chase take over the role from Jennifer Buist?
A. No. Previous to Amanda Chase it was done out in corporate by Heather McKenzie, and Jen Buist was previous to Heather McKenzie.

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Q. Just forgive me, just give me one second because I ask a lot of questions that were already covered, and it's a lot easier for me just to look at my notes than to ask you all those questions again.
As part of your role on the suspicious order monitoring steering committee, have you had a chance to review some chargeback data?
A. Yes.
Q. And this may have been covered earlier, but do you recall when chargeback data started being used by the suspicious order monitoring program at Mallinckrodt?
A. So we reviewed some e-mails earlier today that gave a ballpark, but I don't remember exactly when.
Q. And have you ever had occasion for yourself to request chargeback data?
A. For myself?
Q. Well, let me back up.
Do you maintain the chargeback data?
A. No.
Q. If you needed a chargeback report run, how would you go about effectuating that?

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A. I would contact the finance analyst that has access to the chargeback system.
Q. And who is that?
A. Currently is Debbie Digby.
Q. And who was it prior to Ms. Digby?
A. I'm not sure who Jennifer was getting -- Jen Buist was getting them from.
Q. And then have you ever had occasion to ask for chargeback data?
A. Yes.
Q. Any time when that request for chargeback data was refused?
A. No.
Q. You testified earlier that when Mallinckrodt terminated chargebacks to a pharmacy you reported this to the DEA and Mallinckrodt would inform the DEA through a letter. Do you remember that testimony?
A. Yes.
Q. Did Mallinckrodt maintain a copy of the letter that it sent to the DEA?
A. Yes.
Q. And did you send that letter?
A. I send them currently. Previous to me

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would have been Jen Buist or Heather McKenzie.
Q. Okay. And when did you start sending them?
A. When SOM program transferred to Hobart back in April of 2017.
Q. Okay. Thank you.
I'm going to hand you a document that we marked as Exhibit 46.
(Whereupon, Mallinckrodt-Spaulding-46 was marked for identification.)
BY MR. GESTEL:
Q. And I promise you that we're near the end.
You've been handed a document that's been marked as Exhibit 46. At the top of it, the title of this document is the "HZQS - Controlled Substances Compliance Responsibilities Associated with Anti-Diversion."
Did I read that correctly?
A. Yes.
Q. And you see the revision date is March 11, 2015.
Do you see that?

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A. Yes.
Q. Do you know if this is -- continues to be the current policy?
A. I don't.
Q. Do you maintain the policies?
A. I do not.
Q. But you know that based on the record here that this was at least the portion that was in effect on March 11, 2015?
A. Based on this document, yes.
Q. And then if there are subsequent revisions, does the revision date gets updated and it supersedes the date of the previous revision?
A. Correct, the next revision would move the March -- 03/11/2015 to supersedes date, and then become the new date.
Q. Got it.
I've handed you a document that we'll mark as Exhibit 47.
(Whereupon, Mallinckrodt-Spaulding-47 was marked for identification.)
BY MR. GESTEL:
Q. And this document is another SOM

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written policy. This one is entitled "Identification, Investigation, and Reports of Controlled Substances Suspicious Orders."
Did I read that correctly?
A. Yes.
Q. I don't want to belabor this too much, but same thing with regard to the effective date and supersede date is the same as the document that preceded this?
A. Yes.
Q. Do you know if this is the current in-force version of this policy?
A. I don't.
(Whereupon, Mallinckrodt-Spaulding-48 was marked for identification.)
BY MR. GESTEL:
Q. You're going to notice a trend here. Exhibit 48 (handing). Once again, another SOM policy, this one entitled "Controlled Substances Compliance Responsibilities Associated with Suspicious Order Monitoring."
Did I read that correctly?
A. Yes.
Q. And then there's a revision date of

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February 19, 2015, correct?
A. Yes.
Q. And then a supersedes date of a previous policy of November 14, 2013, right?
A. Yes.
Q. And then once again, we can assume that this is the policy that went into effect on February 19, 2015?
A. Yes.
Q. And then do you know if this is the current policy in effect?
A. I don't.
Q. But if it was revised, there would be a new revision date with the supersede date replaced with this February 19, 2015 date?
A. Correct, if it had been approved.
Q. That was my last policy. I hand you Exhibit Number 49.
(Whereupon, Mallinckrodt-Spaulding-49 was marked for identification.)
BY MR. GESTEL:
Q. This is an e-mail from you dated September 18, 2015 to Carrie Johnson, correct?
A. Yes.

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Q. And it has -- carries the title "UO" -- or subject "UOR Program Review," right?
A. Yes.
Q. What is the UOR program?
A. Unusual order reports.
Q. And then if you flip back, you see that there are various attachments to this e-mail, right?
A. Yes.
Q. Do you recall sending this e-mail?
A. I don't, no.
Q. Any reason to believe that you did not send the e-mail?
A. No.
Q. And then if you flip back to the last page, there is a document entitled "Excluded Items within the UOR scope of JDE."
Did I read that correctly?
A. Yes.
Q. What does that mean?
A. So there's certain products that we make on behalf of other manufacturers, such as this Methylin Chewable, Methylin Oral, Tussicaps, and we do not distribute to the

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market. So we're a contract marketing organization for another manufacturer.
Q. Okay. And then do you see there's a chart that says, two columns, "Reason" and then "Definition"?
Do you see that?
A. Yes.
Q. And then there are three reasons listed. Under the second one, there's "Xartemis XR." Did I say that correctly?
A. Yeah, Xartemis.
Q. Xartemis.
And it says "added to table on March 12, 2014. XXR deemed by SOM Team not likely to be diverted into other than legitimate medical channels."
Did I read that correctly?
A. Yes.
Q. What does that mean?
A. It's a branded product, and it's very small volume, very expensive, so there's not a lot of it moving.
Q. And so what does it mean that "XXR deemed by SOM Team not likely to be diverted"?

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A. It's -- XXR is the abbreviation for Xartemis XR.
Q. Got it.
Does this mean that orders for this particular item are not being run through the algorithm?
A. Yes.
Q. And then the same thing here on the next reason, "Generic Exalgo"?
A. Correct.
Q. It says it's added to the table on May 15, 2014.
A. Added to the table, yes.
Q. And then "Generic Exalgo deemed by SOM Team not likely to be diverted into other than legitimate medical channels."
Did I read that correctly?
A. Correct.
Q. Does that mean that orders for the generic Exalgo are also not being run through the algorithm?
A. For both products until they were removed on January 22, 2015, and then they were being run.

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Q. Got it. Actually that was my next question.
So when you say removed from the list, it means removed from this carveout list from the suspicious order monitoring -- or I'm sorry, the algorithm processing?
A. Correct, because they were both new products that were launched, so there was no history in the market to be able to measure volumes against for previous orders.
Q. Got it.
So -- but then beginning on January 22, 2015, these two items were then added to the algorithm?
A. Correct, because now we had a history to know what customers would be ordering of it to look at.
Q. Got it.
And is that true through today, that those are being ran through the algorithm?
A. Both products are discontinued, but yes.
Q. Got you.
You went through with Mr. Gotto

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some -- the memorandum of understanding entered between Mallinckrodt and the United States Department of Justice.
Do you recall that testimony?
A. The memorandum of agreement, yes.
Q. Yes.
Were you disciplined at all as a result of the allegations by the Department of Justice that led to that MOA?
A. No.
Q. Are you aware of anyone at Mallinckrodt that was disciplined as a result of the allegations that gave rise to the July, 2017 MOA with the United States Department of Justice?
A. No.
Q. This must be music to your ears, Ms. Spaulding, but that's all I have.
THE VIDEOGRAPHER: The time is 5:40 p.m., and we're off the record.
(Whereupon, a recess was taken.)
THE VIDEOGRAPHER: The time is 5:40 p.m., and we're on the record.
EXAMINATION

BY MR. O'CONNOR:
Q. Ms. Spaulding, I promise to be quick.
Can you please take a look at Exhibit Number 41, the memorandum of agreement? I just want to make sure we have a very clear record on this.
Earlier today Mr. Gotto questioned you with regard to the Background section on Page 1 of this agreement.
Do you recall that testimony?
A. Yes.
Q. Again, just so we have a clear record, after you had a chance to review the language of that Background section with Mr. Gotto, do you agree with any of the allegations the United States was making against Mallinckrodt in these paragraphs 1 through 7?
A. No.
Q. Okay. And specifically you don't agree, or do you agree with the United States -- strike that.
Do you agree with the allegations the United States is making in paragraph 3 specifically?

A. No.
Q. And do you agree with the allegations the United States is making in paragraph 5?
A. No.
Q. Okay. If you could turn to Page 3, I'll direct your attention to subparagraph B, as in boy, Mr. Gotto asked you a series of questions about paragraph B. Do you recall that?
A. Yes.
Q. And how would you characterize the issues that are addressed in paragraph B?
MR. GOTTO: Object to form.
A. They are all documentation --
BY MR. O'CONNOR:
Q. Okay.
A. -- instances.
Q. Are you aware of any evidence to suggest that any of the issues described in paragraph B led to any controlled substance leaving the Hobart facility?
MR. GOTTO: Object to form.
A. No.
MR. O'CONNOR: Okay. All right.

That's it.
Go off the record.
THE VIDEOGRAPHER: The time is 5:43 p.m. This deposition has concluded, and we are off the record.
(Whereupon, the deposition was concluded.)

COMMONWEALTH OF MASSACHUSETTS)
SUFFOLK, SS.)
I, MAUREEN O'CONNOR POLLARD, RMR, CLR, and Notary Public in and for the Commonwealth of Massachusetts, do certify that on the 5th day of February, 2019, at 9:06 o'clock, the person above-named was duly sworn to testify to the truth of their knowledge, and examined, and such examination reduced to typewriting under my direction, and is a true record of the testimony given by the witness. I further certify that I am neither attorney, related or employed by any of the parties to this action, and that I am not a relative or employee of any attorney employed by the parties hereto, or financially interested in the action.
In witness whereof, I have hereunto set my hand this 7th day of February, 2019.

_____
MAUREEN O'CONNOR POLLARD, NOTARY PUBLIC
Realtime Systems Administrator
CSR #149108

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

ERRATA

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do Hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

Eileen Spaulding DATE

Subscribed and sworn
To before me this
_____ day of _____, 20____.
My commission expires: _____

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Notary Public

LAWYER'S NOTES

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